Preliminary PRIA3 Interpretations (9/4/12 draft)

Registration Division					
EPA No.	**CR No.**	**Action**	**Interpretation**	**Decision time (months)** **FY 13**	**FY 13 Registration Service Fee ($)**
			Table 1. New Active Ingredients		
R010	1	New Active Ingredient, Food use (2) (3)	An application that proposes a food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The use requires the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application for a new active ingredient are covered by the base fee for the application in this category if submitted in the same package. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert	24	569,221

			ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R020	2	New Active Ingredient, Food use; reduced risk (2) (3)	An application that proposes a food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The use requires the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application for a new active ingredient are covered by the base fee for the application in this category if submitted simultaneously. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. A "reduced risk" (http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency's Reduced Risk Committee will evaluate the submission and make the determination, based on criteria and guidance listed in PR Notice 97-3 and in FIFRA 3(c)(10)(B) (-iv), whether the requested use(s) qualify as "reduced risk" when compared to currently registered pesticides for the same use(s). The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that	18	569,221

			the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as "reduced risk" by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to category R010, and the action will receive the R010 decision review timeframe. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R040	3	New Active Ingredient, Food use; Experimental Use Permit application; establish temporary tolerance;	An Experimental Use Permit (EUP) application for food use(s) of an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The application proposes a food use. The use requires the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted simultaneously. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses	18	419,502

		submitted before application for registration; credit 45% of fee toward new active ingredient application that follows (3)	involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. The Agency will not accept a certification for crop destruct once the review clock has started. A change to a crop destruct application would require the applicant to withdraw their application and start the process application again. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R060	4	New Active Ingredient, Non-food use; outdoor (2) (3)	An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not indoor as described in the indoor category. All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Non-food outdoor uses could include, for example, treatment of ornamentals in a shade house or turf uses. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor	21	395,467

			required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R070	5	New Active Ingredient, Non-food use; outdoor; reduced risk (2) (3)	An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not indoor as described in the indoor category. All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Non-food outdoor uses could include, for example, treatment of ornamentals in a shade house or turf uses. A "reduced risk" (http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency's Reduced Risk Committee will evaluate the submission and make the determination, based on criteria and guidance listed in PR Notice 97-3 and in FIFRA 3(c)(10)(B) (-iv), whether the requested use(s) qualify as "reduced risk" when compared to currently registered pesticides for the same use(s). The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as "reduced risk" by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the category R060 and the action will receive R060 decision review timeframe. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is	16	395,467

			submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R090	6	New Active Ingredient, Non-food use; outdoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows (3)	An Experimental Use Permit (EUP) application for non-food use(s) of an active ingredient that is not contained as an active ingredient in any currently U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not indoor as described in the indoor category. All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Non-food outdoor uses could include, for example, treatment of ornamentals in a shade house or turf uses. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency	16	293,596

			will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R110	7	New Active Ingredient, Non-food use; indoor (2) (3)	An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Indoor means that the proposed use is for use inside of manmade structures. All indoor non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Some examples of indoor uses are termiticide structural protection, and indoor residential treatments (i.e. cockroach treatments). Treatment of ornamentals in a shade house is classified as outdoor uses and is not covered in this category. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed	20	219,949

			upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R120	8	New Active Ingredient, Non-food use; indoor reduced risk (2) (3)	An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Indoor means that the proposed use is for use inside of manmade structures. All indoor non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Some examples of indoor uses are termiticide structural protection and indoor residential treatments (i.e. cockroach treatments). Treatment of ornamentals in a shade house is classified as outdoor uses and is not covered in this category. A "reduced risk" (http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency's Reduced Risk Committee will evaluate the submission and make the determination, based on criteria and guidance listed in PR Notice 97-3 and in FIFRA 3(c)(10) (B) (-iv), whether the requested use(s) qualify as "reduced risk" when compared to currently registered pesticides for the same use(s). The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as "reduced risk" by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the category R110 and the action will receive the R110 decision review timeframe. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee.	14	219,949

			The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R121	9	New Active Ingredient, Non-food use; indoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows (3)	An Experimental Use Permit (EUP) application for non-food use(s) of an active ingredient that is not contained as an active ingredient in any currently U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Indoor means that the proposed use is for use inside of manmade structures. All indoor non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Some examples of indoor uses are termiticide structural protection, and indoor residential treatments (i.e. cockroach treatments). Treatment of ornamentals in a shade house is classified as an outdoor use and is not covered in this category. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At this time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.	18	165,375
R122	10	Enriched isomer(s) of registered	An application that proposes using an enriched isomer of an active ingredient**,** where such enriched isomer is not currently contained as an active ingredient in any U.S. registered pesticide product. This	18	287,643

		mixed-isomer active ingredient (2) (3)	category consists of active ingredients that are a variation on the molecular structure or composition of a registered product and which will cite at least some of the generic data conducted with a registered product. If a food use is included in this new active ingredient package, the use may require the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. If a tolerance or exemption from the requirement of a tolerance is required, the application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application. All uses (food and non-food) included in the original application or petition for each new active ingredient are covered by the base fee for the application in this category if submitted in this package. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R123	11	New Active Ingredient, Seed treatment only;	An application for seed treatment only that proposes a food use or non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product that is not expected to result in residues in raw agricultural commodities. The application submission must contain	18	427,991

		includes agricultural and non-agricultural seeds; residues not expected in raw agricultural commodities (2) (3)	a petition requesting the non-food determination. If a determination is made that the uses do not need a tolerance or exemption from the requirement of a tolerance, then the chemical will be listed in the 40 CFR 180.220 Non-Food Determination section. All uses (food and non-food) included in the original application for each new active ingredient are covered by the base fee for the application in this category if submitted in this package. In order for a food crop seed treatment to be considered in this category, data from a radiotracer study must be available showing no uptake of residues (radioactivity) from treated seed into the aerial portion of the growing crop. Guidance is available at (http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/). If residues occur in the aerial portion of the plant, or if there is no data available to make this determination, seed treatments are considered to be food uses requiring tolerances and fall into a different category**.** All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		

R125 New	12	New Active Ingredient, Seed treatment; Experimental Use Permit application, submitted before application for registration; credit 45% of fee toward new active ingredient application that follows (3)	An Experimental Use Permit (EUP) application for seed treatment only that proposes a food use or non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product that is not expected to result in residues in raw agricultural commodities. All uses (food and non-food) included in the original application for a new active ingredient are covered by the base fee for the application in this category. In order for a food crop seed treatment to be considered in this category, data from a radiotracer study must be available showing no uptake of residues (radioactivity) from treated seed into the aerial portion of the growing crop. Guidance is available at (http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/. If residues occur in the aerial portion of the plant, or if there is no data available to make this determination, seed treatments are considered to be food uses requiring tolerances and fall into a different category**.** All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.	16	293,596

			Table 2. New Uses		
R130	13	First Food Use; Indoor; Food/Food Handling (2) (3)	An application that proposes the first indoor food use. First food use includes a proposed use of any U. S. registered active ingredient for which there is no registered "food use". The use requires the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). Indoor means that the proposed use is for use inside of manmade structures. All indoor food uses included in any original application or petition for the first food use are covered by the base fee for the application in this category if submitted within the original application. Some examples of indoor food uses include use in a food handling and/or processing establishment, use on food crops in a greenhouse, aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, use in home gardens, and uses involving livestock, such as livestock housing, and livestock dips. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested first food use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.	21	173,644

R140	14	Additional food use; Indoor, Food/Food Handling (3) (4)	An application that proposes an additional indoor food use. This category includes a proposed indoor food use of any U. S. registered active ingredient for which there currently is a registered food use. The use requires the establishment of the exemption from the requirement of a tolerance under section 408 of the FFDCA. If residues are reasonably foreseeable or likely to occur in food or feed or around food, the application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). Increases in exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. Indoor means that the proposed use is for use inside of manmade structures. Some examples of indoor food uses include: use in a food handling and/or processing establishment, use on food crops in a greenhouse, aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, use in home gardens, and uses involving livestock, such as livestock housing, and livestock dips. The fee applies to each additional food use requested (i.e. the fee for this category is multiplied by 4 if 4 uses are proposed). If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been registered, then requesting the crop group will count as one additional use. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested additional food use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses.	15	40,518

			Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
R150	15	First Food Use (2) (3)	An application that proposes the first food use. First food use includes a proposed use for any U. S. registered active ingredient for which there is no registered food use. The use requires the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses included in any original application or petition for the first food use are covered by the base fee for the application in this category if submitted within the original application. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant	21	239,684

			the requested first food use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R160	16	First Food Use; Reduced Risk (2) (3)	An application that proposes the first food use. First food use includes a proposed use for any U. S. registered active ingredient for which there is no registered food use. The use requires the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All food uses included in any original application or petition for the first food use are covered by the base fee for the application in this category if submitted within the original application. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. A "reduced risk" (http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency's Reduced Risk Committee will evaluate the submission and make the determination, based on criteria and guidance listed in PR Notice 97-3 and in FIFRA 3(10) (B) (-iv), whether the requested use(s) qualify as "reduced risk" when compared to currently registered pesticides for the same use(s). The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as "reduced risk" by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the category R150 and the action will receive the R150 decision review timeframe. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each	16	239,684

			application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested first food use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R170	17	Additional Food Use (3) (4)	An application that proposes an additional food use. Additional food use includes a proposed food use for any U. S. registered active ingredient for which there currently is an approved food use. The use requires the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. The fee applies to each additional food use requested up to 5 uses (i.e. the fee for this category is multiplied by 4 if 4 uses are proposed). If six or more additional food uses are requested in the application, fee category R190 applies. If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been registered, then requesting the crop group will count as one additional use. Some unusual examples of outdoor uses are livestock uses, (i.e.	15	59.976

			ear tags), livestock dips, and feed through treatments of livestock. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested additional food use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
R175 New	18	Additional food uses covered within a crop group resulting from the conversion of existing approved	An application that proposes an additional food use. Additional food use includes a proposed food use for any U. S. registered active ingredient for which there currently is an approved food use. The use requires the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase	10	59,976

		crop group(s) to one or more revised crop groups (3) (4)	or different method of application will result in the application being treated as a new use. Examples of food uses include: use on foods, for example, corn or apples, aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. The fee applies to conversion of tolerances from one or more pre-existing crop groups/subgroups that have been superseded by the establishment of revised crop groups/subgroups. The application will not contain new data for review in this category. The agency will assess the risks associated with the conversion of the crop group(s) which will require review in our science divisions (HED and EFED). If conversion of a crop group or subgroup requires submission of new data, the action does not belong in this category. The appropriate category will be one of the food use categories (e.g.R170). Some unusual examples of outdoor uses are livestock uses, (i.e. ear tags), livestock dips, and feed through treatments of livestock. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested additional food use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted		

			by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
R180	19	Additional Food Use; Reduced Risk (3) (4)	An application that proposes an additional food use. Additional food use includes a proposed food use for any U. S. registered active ingredient for which there currently is a registered food use. The use requires the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCA. If residues are reasonably foreseeable or likely to occur in food or feed or around food, the application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. The fee applies to each additional food use requested up to 5 uses (i.e. the fee for this category is multiplied by 4 if 4 uses are proposed). If six or more additional food uses are requested in the application, fee category R200 applies. If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been registered, then requesting the crop group will count as one additional use. Some unusual examples of outdoor uses are livestock uses, (i.e. ear tags), livestock dips, and feed through treatments of livestock. A “reduced risk” (http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency’s Reduced Risk Committee will evaluate the submission and make the determination, based on criteria and guidance listed in PR Notice 97-3 and in FIFRA 3(c)(10) (B) (-iv), whether the requested use(s) qualify as “reduced risk” when compared to currently registered pesticides for the same use(s). In the event that any uses do not qualify as reduced risk, the application will not receive the reduced risk decision timeframes. The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the	10	59,976

			event that any uses do not qualify as "reduced risk" by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the category R170, and the action will receive the R170 decision review timeframe. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested additional food use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
R190	20	Additional Food Uses, 6 or more submitted in one	An application that proposes additional food uses. Additional food use includes a proposed food use for any U. S. registered active ingredient for which there currently is a registered food use. The use requires the establishment of, or the exemption from the requirement of a tolerance under section 408 of	15	359,856

		application (3) (4)	the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. The application must propose at least (6) specific additional food or feed crops or 6 or more additional representative commodities for crop subgroups or crop groups. If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been registered, then requesting the crop group will count as one additional use. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested additional food use registrations. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the		

			original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
R200	21	Additional Food Use; 6 or more submitted in one application; Reduced Risk (3) (4)	An application that proposes additional food uses. Additional food use includes a proposed food use for any U. S. registered active ingredient for which there currently is a registered food use. The use requires the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. The application must propose at least (6) specific additional food or feed crops or 6 or more additional representative commodities for crop subgroups or crop groups. If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been registered, then requesting the crop group will count as one additional use. A “reduced risk” (http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency’s Reduced Risk Committee will evaluate the submission and make the determination, based on criteria and guidance listed in PR Notice 97-3 and in FIFRA 3(c)(10) (B) (-iv), whether the requested use(s) qualify as “reduced risk” when compared to currently registered pesticides for the same use(s). In the event that any uses do not qualify as reduced risk, the application will not receive the reduced risk decision timeframes. The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as “reduced risk” by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the category R190 and the action will receive the R190 timeframe.	10	359,856

			All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested additional food use registrations. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
R210	22	Additional food use; Experimental Use Permit application; establish temporary tolerance; no credit	An Experimental Use Permit (EUP) application for a new food use(s) that includes a proposed additional food use for any U. S. registered active ingredient that is currently not registered for the proposed use. The use requires the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). Increases in exposure such as a dosage rate increase or different method of application that will result in a temporary tolerance increase belong to this category. Examples of food uses include:	12	44,431

		toward new use registration (3) (4)	use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. The Agency will not accept a certification for crop destruct once the review clock has started (the "clock" or decision review timeframe starts 21 days after the Agency receives the application and the required fees or approves a fee waiver or fee exemption). A change to a crop destruct application would require the applicant to withdraw their application and start the process application again. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time		

			applies to all of the new uses requested in the application.		
R220	23	Additional food use; Experimental Use Permit application; Crop Destruct Basis; no credit toward new use registration (3) (4)	An Experimental Use Permit (EUP) application for a new food use(s) includes a proposed food for any U. S. registered active ingredient that is currently not registered for the proposed use. Food/feed commodities covered by the pending application(s) must have a certification that all food/feed treated under the EUP will be destroyed or fed to experimental animals for testing purposes only. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application.	6	17,993

			Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
R230	24	Additional use; Non-food; Outdoor (3) (4)	An application that proposes a new non-food use. A non-food use includes a proposed use that is not a food use as described in the food use categories. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. Outdoor use means any use that is not indoor as described in the indoor category. Non-food outdoor uses could include treatment of ornamentals in a shade house, termiticide use around the perimeter of a house and turf uses. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested additional use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application.	15	23,969

			Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
R240	25	Additional use; Non-food, Outdoor, Reduced Risk (3) (4)	An application that proposes a new non-food use. A non-food use includes a proposed use that is not a food use as described in the food use categories. A different pattern in a non-food outdoor use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application that belongs in this category. Outdoor use means any use that is not indoor as described in the indoor category. Examples of non-food outdoor uses are treatment of ornamentals in a shade house, termiticide use around the perimeter of a house, and turf uses. A "reduced risk" (http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency's Reduced Risk Committee will evaluate the submission and make the determination, based on criteria and guidance listed in PR Notice 97-3 and in FIFRA 3(c)(10) (B) (-iv), whether the requested use(s) qualify as "reduced risk" when compared to currently registered pesticides for the same use(s). In the event that any uses do not qualify as reduced risk**,** the application will not receive the reduced risk decision timeframes. The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as "reduced risk" by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the non-reduced risk category and the action will receive the longer timeframes (e.g. from an R240 New Use, Non- Food Use, "reduced risk" to an R230 New Use, Food Use). All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested additional use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application	10	23,969

			without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
R250	26	Additional Use; Non-food; Outdoor; Experimental Use Permit Application; no credit toward new use registration (3) (4)	An Experimental Use Permit (EUP) application that proposes a new non-food use for any U.S. registered active ingredient that is currently not registered for the proposed use. A non-food use includes a proposed use that is not a food use as described in the food use categories. A different pattern in a non-food outdoor use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application that belongs in this category. Outdoor use means any use that is not indoor as described in the indoor category. Fees will not cover any subsequent application for registration of the new use. Non-food outdoor uses could include treatment of ornamentals in a shade house, and turf uses. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to	6	17,993

			reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
R251 New	27	Experimental Use Permit application which requires no changes to the tolerance(s); non-crop destruct basis (3)	An Experimental Use Permit (EUP) application for food use which requires no changes to the existing tolerance(s) and the crop is not destroyed. Any U.S. registered active ingredient that currently has approved tolerance(s) for the proposed use. Due to the extended registration process in certain states, this category provides the ability to conduct an EUP without the need for crop destruct or for establishing temporary tolerance(s) while the state registration is under review. This category would allow the conduct of research in States for a new use or new application method on a crop for which tolerance(s) were already federally approved. For example, in order to get a California EUP, CA requires a Federal EUP to do testing. Testing may be required by CA for an aerial application when only the ground application method is approved in the state. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. All of the inerts used in the product must be approved for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA	8	17,993

			decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R260	28	New Use, Non-food, Indoor (3) (4)	An application that proposes a new non-food use. A non-food use includes a proposed use that is not a food use as described in the food use categories. A different pattern in a non-food indoor use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application that belongs in this category. The proposed use is for use inside of manmade structures and is not a food use. Some examples of indoor uses are termiticides and indoor residential treatments (i.e. cockroach treatments). Treatment of ornamentals in a shade house is classified as outdoor uses and is not covered in this category. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested non-food use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses.	12	11,577

			Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
R270	29	New Use, Non-food, Indoor, Reduced Risk (3) (4)	An application that proposes a new non-food use. A non-food use includes a proposed use that is not a food use as described in the food use categories. A different pattern in a non-food indoor use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application that belongs in this category. The proposed use is for use inside of manmade structures and is not a food use**.** Some examples of indoor uses are termiticides and indoor residential treatments (i.e. cockroach treatments). Treatment of ornamentals in a shade house is classified as outdoor uses and is not covered in this category**.** A "reduced risk" (http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency's Reduced Risk Committee will evaluate the submission and make the determination, based on criteria and guidance listed in PR Notice 97-3 and in FIFRA 3 (c (10) (B) (-iv), whether the requested use(s) qualify as "reduced risk" when compared to currently registered pesticides for the same use(s). In the event that any uses do not qualify as reduced risk, the application will not receive the reduced risk decision timeframes. The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as "reduced risk" by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the non-reduced risk category and the action will receive the longer timeframes (e.g. from an R270 New Use, Non-Food Use "reduced risk" to an R260 New Use, Non-Food Use). All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA	9	11,577

			decision review time due date which specifies any label changes that have to be made in order to grant the requested non-food use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
R271	30	New use; non-food; indoor; Experimental Use Permit application; no credit toward new use registration (3) (4)	An Experimental Use Permit (EUP) application for a new non-food use(s) includes a proposed non-food use for any U. S. registered active ingredient that is currently not registered for the proposed use. A non-food use includes a proposed use that is not a food use as described in the food use categories. Increases in exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The proposed use is for use inside of manmade structures and is not a food use. Some examples of indoor uses are termiticide structural protection and indoor residential treatments (i.e. cockroach treatments). Treatment of ornamentals in a shade house is classified as outdoor uses and is not covered in this category.	6	8,820

			All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
R273	31	Additional use; seed treatment; limited uptake into Raw Agricultural Commodities; includes crops with established	An application that proposes an additional seed treatment use only for any U.S. registered active ingredient for food use or non-food use seed treatment that is not expected to result in residues in raw agricultural commodities. In order for a seed treatment to be considered in this category when proposed for seed treatment use on a food crop, data from a radiotracer study must be available showing no uptake of residues (radioactivity) from treated seed into the aerial portion of the growing crop. Guidance is available at (http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/860_Residue_Chemistry	12	45,754

		tolerances (e.g., for soil or foliar application); includes food and/or non-food uses (3) (4)	_Test_Guidelines/Series/). The application submission must contain a petition requesting the non-food determination. If a determination is made that the uses do not need a tolerance or exemption from the requirement of a tolerance, then the chemical will be listed in the 40 CFR 180.220 Non-Food Determination section. If residues occur in the aerial portion of the plant, or if there is no data available to make this determination, seed treatments are considered to be food uses requiring tolerances and fall into a different category. Examples of food uses are corn, soybean, and wheat. If a seed treatment use is proposed on ornamental seed or other non-food use seed treatment then the application would be in this category because it is known, without consideration of any data, that a tolerance is not required. The fee applies to each seed treatment use requested up to 5 uses (i.e. the fee for this category is multiplied by 4 if 4 seed uses are proposed). If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been registered, then requesting the crop group will count as one additional use**.** If a numerical tolerance needs to be established, the application does not belong in this category. If six or more seed treatment uses are being proposed, this is not the correct category (see R274). All of the inerts used in the product must be approved for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested additional use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new		

			decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
R274	32	Additional uses; seed treatment only; 6 or more submitted in one application; limited uptake into Raw Agricultural Commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food and/or non food uses (3) (4)	An application that proposes an additional seed treatment use only for any U.S. registered active food use or non-food use for an active ingredient that is currently contained as an active ingredient in any U.S. registered pesticide product. The application must propose at least (6) specific seed treatment uses or 6 or more representative seeds for crop subgroups or crop groups. In order for a seed treatment to be considered in this category, data from a radiotracer study must be available showing no uptake of residues (radioactivity) from treated seed into the aerial portion of the growing crop. Guidance /) is available at (http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series. The application submission must contain a petition requesting the non-food determination. If a determination is made that the uses do not need a tolerance or exemption from the requirement of a tolerance, then the chemical will be listed in the 40 CFR 180.220 Non-Food Determination section. If residues occur in the aerial portion of the plant, or if there is no data available to make this determination, seed treatments are considered to be food uses requiring tolerances and fall into a different category. Examples of food uses are corn, soybean, and wheat. If a seed treatment use is proposed on ornamental seed or other non-food use seed treatment use, then the application would be in this category because it is known, without consideration of any data, that a tolerance is not required. If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been registered, then requesting the crop group will count as one additional use**.** If a numerical tolerance needs to be established, the application does not belong in this category. All of the inerts used in the product must be approved for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested additional use registrations. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and	12	274,523

			supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		

			Table 3. Import and Other Tolerances		
R280	33	Establish Import tolerance; new active ingredient or first food use (2) [This footnote modified for an import tolerance]	A petition for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product or a petition for the first food use. The petition proposes the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The food or feed commodities are imported into the U.S. The applicant is not seeking a domestic registration for the new active ingredient and no tolerances exist in the U.S. for the active ingredient. For the first food use, there is a currently U.S. registered non-food use product and the applicant is not seeking a domestic registration for the proposed food use. All food tolerances included in the original petition for a new active ingredient or a first food use are covered by the base fee for that application in this category if submitted simultaneously. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. Each application for a new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee.	21	289,407
R290	34	Establish Import tolerance; Additional new food use	A petition application that proposes the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA for an active ingredient that has a currently approved U.S. food tolerance. The food or feed commodities are imported into the US. If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been established, then requesting the crop group will count as one additional use**.** The applicant is not seeking a domestic registration for the additional food use. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where	15	57,882

			food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags.		
R291	35	Establish import tolerances; additional food uses; 6 or more crops submitted in one petition	A petition application that proposes the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA for an active ingredient that has a currently approved U.S. food tolerance. The food or feed commodities will be imported into the US. The applicant is not seeking a domestic registration for the additional food use. The petition must propose at least (6) specific food or feed crops or 6 or more representative commodities for crop subgroups or crop groups. If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been established, then requesting the crop group will count as one additional use	15	347,288
R292	36	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	A petition to amend an existing tolerance on domestic or imported crops and for which there is not a related label amendment request necessitating the proposed tolerance amendment.. This may be a request to increase or decrease an existing tolerance currently established under section 408 of the FFDCA. The fee for this category applies to each additional food use to which the requested tolerance amendments apply, up to 5 uses (i.e. the fee for this category is multiplied by 4 if 4 uses are proposed). If tolerance amendments are being requested for six or more uses, the fee category R297 applies. This category is applicable when a tolerance amendment is being requested but no related label amendment is necessary or being requested. Examples of situations to which this category might apply include but are not limited to requests to amend an existing tolerance (decrease level), requests to increase an existing tolerance to reflect residue data demonstrating higher observed residues than the existing tolerance, or requests to move an existing tolerance from one paragraph to another within the citation in 40 CFR Part 180. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags.	11	41,124
R293	37	Establish tolerance(s) for inadvertent	A petition that proposes to establish tolerances for each non-target crop resulting in inadvertent residues. The active ingredient is currently contained in a pesticide product registered in the U.S. The fee to establish tolerances for each crop will be multiplied by the number of crops in the petition (i.e. 5	12	48,510

		residues in one crop; applicant-initiated	crops, the fee will be multiplied 5 times the fee for this category). If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been registered, then requesting the crop group will count as one additional use.		
R294	38	Establish tolerances for inadvertent residues; 6 or more crops submitted in one application; applicant-initiated	A petition that proposes to establish tolerances for 6 or more non-target crops resulting in inadvertent residues. The active ingredient is currently contained in a pesticide product registered in the U.S. If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been registered, then requesting the crop group will count as one additional use**.**	12	291,060
R295	39	Establish tolerances(s) for residues in one rotational crop in response to a specific rotational crop application; applicant-initiated	A petition that proposes to establish tolerances for each crop that is rotated and results in rotational crop residues. The active ingredient is currently contained in a pesticide product registered in the U.S. The fee to establish tolerances for each crop will be multiplied by the number of crops in the petition (i.e. 5 crops, the fee will be multiplied 5 times the fee for this category). If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been registered, then requesting the crop group will count as one additional use**.**	15	59,976
R296	40	Establish tolerances for residues in rotational crops in response to a specific rotational crop petition; 6 or more crops submitted in one application; applicant-initiated	A petition that proposes to establish tolerances for 6 or more crops that are rotated and results in rotational crop residues. The active ingredient is currently contained in a pesticide product registered in the U.S. If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been registered, then requesting the crop group will count as one additional use.	15	359,856
R297	41	Amend 6 or more established	A petition to amend six or more existing tolerances on domestic or imported crops and for which there is	11	246,744

New		tolerances (e.g. decrease or increase) in one petition; domestic or import; applicant initiated	not a related label amendment request necessitating the proposed tolerance amendments. This may be a request to increase or decrease existing tolerances currently established under section 408 of the FFDCA. This category is applicable when tolerance amendments are being requested but no related label amendment is necessary or being requested. Examples of situations to which this category might apply include but are not limited to requests to amend 6 or more existing tolerances to harmonize with international MRLs, requests to increase 6 or more existing tolerances to reflect residue data demonstrating higher observed residues than the existing tolerances, or requests to move 6 or more existing tolerances from one paragraph to another within the citation in 40 CFR Part 180. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags.		
R298 New	42	Amend an established tolerance (e.g., decrease or increase); domestic or import; submission of amended labels (requiring science review) in addition to those associated with the amended tolerance; applicant-initiated (3)	An application and/or a petition request to amend an existing tolerance on domestic or imported crops in which an associated label amendment is also submitted. This may be a request to increase or decrease an existing tolerance(s) currently established under section 408 of the FFDCA. The fee for this category applies to tolerance amendments for each food use requested up to 5 uses (i.e. the fee for this category is multiplied by 4 if tolerance amendments for 4 uses are proposed) to which the label amendments apply. If tolerance and label amendments are being requested for six or more uses, the fee category R299 applies. This category (R298) applies to requests to a change in the labeled use pattern in a way which results in the need for the tolerance to be amended; often residue data supporting the tolerance amendment is included in the request. Examples of label changes that can require changes in tolerances include but are not limited to: changes in application rates, application frequency, application timing, application method or a change in PHIs); Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. All of the inerts used in this product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant	13	53,120

			the requested tolerance amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R299 New	43	Amend 6 or more established tolerances (e.g., decrease or increase); domestic or import; submission of amended labels (requiring science review) in addition to those associated with the amended tolerance; applicant-initiated (3)	An application and/or a petition request to amend six or more existing tolerances on domestic or imported crops in which an associated label amendment is also submitted. This may be a request to increase or decrease existing tolerances currently established under section 408 of the FFDCA. This category applies to requests to a change to the labeled use pattern in a way which results in the need for existing tolerances to be amended; often residue data supporting the tolerance amendments is included in the request Examples of label changes that can require changes in tolerances include but are not limited to: changes in application rates, application frequency, application timing, application method or a change in PHIs). Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. All of the inerts used in this product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested tolerance amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.	13	258,740

			Table 4. New Products		
R300	44	New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; no data review on acute toxicity, efficacy or CRP -- only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits	An application for registration of an end-use or a manufacturing use pesticide product that is substantially similar or identical in its uses and/or formulation to products that are currently registered or differ only in ways that would not significantly increase the risk of unreasonable adverse effects. The applicant must identify the similar products for all active ingredients in the proposed product. To fit this category, all applications require the following: • A data matrix is required with the application. • Product chemistry data (Group A and B) unless the product is identical (e.g. 100% repackaged product). In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • All inert ingredients must already be approved for the applicable uses in the product. • The active ingredient listed on the CSF must be an EPA registered product**.** • In all cases, the applicant must identify the currently registered similar product for this category. • Acute toxicity requirements must be addressed by using: 1) cite-all method or 2) selective data citation where the applicant owns all required data or; the applicant submits specific authorization letter from data owner. The application is not in this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted or cited and must be reviewed to support the application. Data that are selectively cited to support the application must have already been reviewed by the Agency for the same uses, formulation type, active ingredient and claims. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category. Companion animal	4	1,434

		specific authorization letter from data owner. Category also includes 100% re-package of registered end use or manufacturing-use product that requires no data submission nor data matrix (2) (3)	end use products must be 100% compositionally identical to a currently registered product to be considered in this category Substantially similar: Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the proposed product bears the same use patterns. Adding use patterns or changing existing use patterns (other than deleting them) would exclude the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable. Identical**:** Same composition and use patterns as a currently registered end use product. Manufacturing Use Product: A 100% re-package of a manufacturing use product that requires no data submission or data matrix is covered by this category. Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that unregistered source of the active ingredient for another end use product, the active ingredient is considered unregistered. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R301	45	New product; or similar combination product (already registered) to an	An application for registration of an end-use pesticide product that is substantially similar or identical in its uses and/or formulation to products that are currently registered or differ only in ways that would not significantly increase the risk of unreasonable adverse effects. The applicant must identify the similar products for all active ingredients in the proposed product. To fit this category all applications require	4	1,720

		identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner (2) (3)	the following: • A data matrix is required with the application. • Product chemistry data (Group A and B) unless the product is identical. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • All inert ingredients must already be approved for the applicable uses in the product. • The active ingredient listed on the CSF must be an EPA registered product. • In all cases, the applicant must identify the currently registered similar product for this category. • Acute toxicity, efficacy, public health pest efficacy, and/or child resistant packaging data requirements must be addressed by using: 1) the cite-all method, or 2) selective data citation where the applicant does not own all required data and does not have a specific authorization letter from the data owner. If review of data is needed, this application does not fall within this category. The application is not in this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted or cited and must be reviewed to support the application. Data that are selectively cited to support the application must have already been reviewed by the Agency for the same uses, formulation type, active ingredient and claims. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category. Companion animal end use products must be 100% compositionally identical to a currently registered product to be considered in this category An application proposed as a 100% re-packaged product does not fall within this category (see category R300). Substantially similar: Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the proposed product bears the same use patterns. Adding use patterns or changing existing use patterns (other than deleting them) would exclude the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable. Identical**:** Same composition and use patterns as a currently registered end-use product. Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a		

			manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that unregistered source of the active ingredient for another end use product, the active ingredient is considered unregistered. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R310	46	New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; requires review of data package within RD only; includes data and/or waivers of data for only:	An application for registration of an end-use or manufacturing use pesticide product that is not substantially similar or identical in its uses and formulation to products that are currently registered. To fit this category all applications require the following: • A data matrix is required with the application. • Product chemistry data (Group A and B). In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • All inert ingredients must already be approved or pending before the Agency for the applicable uses in the product. • Acute toxicity, efficacy, public health pest efficacy, and/or child resistant packaging data requirements must be addressed by using: 1) the cite-all method, or 2) selective data citation which includes submitting required data. A rationale for a waiver or bridging of these data falls within this category. An application proposed as a 100% re-packaged product does not fall within this category (see category R300). If an applicant owns the generic data and therefore does not qualify for the formulator's exemption, the new product application belongs in this category. The application does not fall into this category if it contains a request to waive generic data or a request to review any generic data.	7	4,807

		- product chemistry and/or - acute toxicity and/or -public health pest efficacy and/or Child resistant packaging (2) (3)	Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that unregistered source of the active ingredient for another end use product, the active ingredient is considered unregistered. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new end-use product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R314 New	47	New end use product containing two or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active	An application for registration of a new end-use product that contains more than one registered conventional active ingredient. The active ingredients have never been registered as this combination before. The proposed label has the same uses as those found on the registered product labels for the single active ingredients. Each active ingredient must use a registered source of active ingredient. Any science review must be within RD only. All of the inerts used in the product must be approved or pending with the Agency for the applicable uses. To fit this category all applications require the following: Certification with Respect to Citation of Data and a data matrix Product chemistry data If applicable, acute toxicity, efficacy, and or child resistant packaging data requirements must be addressed by using; (1) the cite-all method; (2) selective data citation. A rationale for a waiver or bridging of these data can be submitted.	8	6,009

		ingredients; requires review of data package within RD only; includes data and/or waivers of data for only: - product chemistry and/or - acute toxicity and/or – public health pest efficacy and/or – child resistant packaging (2) (3)	This category does not include applications that require a determination on whether data can be bridged or translated to other formulation types (for the individual active ingredients). Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that unregistered source of the active ingredient for another end use product, the active ingredient is considered unregistered. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new end-use product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R315 New	48	New end-use non-food animal product with submission of two or more target animal safety studies; includes data and/or waivers of data for only: Product chemistry and/or Acute toxicity	An application for registration of an end-use pesticide animal product that is not substantially similar or identical in its uses and formulation to a product currently registered. For example, spot-on and flea collars products are generally labeled animal specific, in that a product is labeled for dogs or cats, but not generally both, shampoos and sprays may be labeled for both species (dogs and cats). To fit this category all applications require the following: • A data matrix is required with the application. • Product chemistry data (Group A and B) and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. If the source of the active ingredient in this application is not registered; the decision review time line will be the longest of the associated application (see timeline for - R333 or R334). • All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. In those cases where the product relies upon a pending inert clearance, the new companion animal studies must be conducted with the pending inert in the tested product as it is intended to be marketed and sold as the end use product.	9	8,000

		and/or Public health pest efficacy and/or Animal safety studies and/or Child resistant packaging (2) (3)	• Acute toxicity, public health pest efficacy, child resistant packaging data, companion animal safety data and/or requirements must be addressed by using: 1) the cite-all method, or 2) selective data citation which includes submitting required data. A rationale for a waiver or bridging of these data falls within this category. • Appropriate companion animal safety studies based upon the specific label claims in the proposed label. For example, if the proposed end use product label claim is to use the product on 12 week old kittens weighing ≥3 lbs and on breeding cats, then two companion animal studies are required: the first on using kittens ≥ 12 weeks of age and weighing at least 3 lbs. and a second study on pregnant and nursing adult cats. Each of these studies must demonstrate an adequate margin of safety. An application proposed as a 100% re-packaged product does not fall within this category (see category R300). If an applicant owns the generic data and therefore does not qualify for the formulator's exemption, the new product application belongs in this category. The application does not fall into this category if it contains a request to waive generic data or a request to review any generic data. Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that unregistered source of the active ingredient for another end use product, the active ingredient is considered unregistered. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new end-use product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R320	49	New product; new physical form; requires data	An application for registration of a pesticide product that is not substantially similar or identical in its uses or formulation to products that are currently registered. A change in the formulation type or timing of application for the registered physical form that would require residue data	12	11,996

		review in science divisions (2) (3)	(http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/860_Residue_Chemistry Test_Guidelines/Series/), environmental fate data (http://www.epa.gov/oppefed1/ecorisk_ders/terrestrial_field_dissipation.htm#IC), and/or ecotoxicity, exposure data, etc., to support the change. For example this includes a change in the formulation that would change the way a product is applied (i.e. spot-on treatments, controlled release formulation), a change in the toxicity and/or exposure profile of the product, a pre-mix product that is not currently registered that requires science review per current guidelines, a change in the application rates or PHI, animal products with rate depletion data, change in the formulation, e.g. going from a liquid to a solid, etc. Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that unregistered source of the active ingredient for another end use product, the active ingredient is considered unregistered. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R331	50	New product; repack of identical registered end-use product as a manufacturing-use product; same	An application for registration of a manufacturing use pesticide product that is identical in its formulation and uses to end use products that are currently registered. To fit this category all applications require the following: • A formulator's Exemption statement • The applicant must identify the EPA-registered identical product for this category • The active ingredient listed on the CSF must be an EPA-registered product in order to satisfy the	3	2,294

		registered uses only (2) (3)	data requirements for the active ingredient. If the use pattern for the proposed product differs from the currently registered product, then additional data are required and the application does not fall within this category (see applicable new use categories). Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that unregistered source of the active ingredient for another end use product, the active ingredient is considered unregistered. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R332	51	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of completely new generic data package; registered uses only; requires review in RD and	An application for registration of a manufacturing use pesticide product that is not substantially similar or identical in its formulation to products that are currently registered. New manufacturing use product is any product intended (labeled) for formulation or repackaging into an end use formulated pesticide product. This product does not contain directions for use of the product as distributed or sold, or after combination by the user with other substances. To fit this category all applications require the following: • A data matrix is required with the application. • Product chemistry data (Group A and B). • Acute toxicity data must be addressed by submitting data or using: selective data citation. A rationale for a waiver or bridging of these data falls within this category. • The source of the active ingredient is unregistered • The proposed uses must already be on currently registered products. • The applicant must cite the similar product with the proposed uses. • The application contains generic data such as toxicity, environmental fate and/or eco-toxicity.	24	256,883

		science divisions (2) (3)	Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that unregistered source of the active ingredient for another end use product, the active ingredient is considered unregistered. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new manufacturing-use product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R333 New	52	New product; MUP or end use product with unregistered source of active ingredient; requires science data review; new physical form; etc. Cite-all or selective data citation where applicant owns all required data (2) (3)	An application for registration of a new product (MUP or end use product). New manufacturing use product is any product intended (labeled) for formulation or repackaging into an end use formulated pesticide product. The active ingredient is not a new active ingredient, but either (1) one that claims to be substantially similar or identical to another active ingredient which is currently registered (as referenced by EPA registration number) and has the selective data citation used, or (2) an end use product which claims to be substantially similar or identical in its formulation to another end use product that is currently registered for which the selective data citation was used, but the active ingredient used in the formulation is derived from an unregistered source (i.e., does not have a EPA registration number). To fit this category all applications require the following: • A data matrix is required with the application. • Two sets of product specific product chemistry data and 2 CSF's are required: 1) product chemistry (Group A and B) on the unregistered source of the active ingredient and CSF. The applicant must identify to the Agency the toxicity of the impurities associated with the active ingredient; particularly impurities of toxicological significance (at any level). The impurity profile of the unregistered source of the active ingredient will be compared to the registered	10	17,993

			source and if new impurities of toxicological concern are found, then the application is routed to HED for review. If the data on the unregistered source was previously reviewed by the Agency, please cite the MRID and/or Reg number in the cover letter to the application and the date of Agency review; 2) Product chemistry data (Group A and B) for the end use product and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. • Acute toxicity, public health pest efficacy, companion animal safety data and/or child resistant packaging data requirements must be addressed by using: 1) cite-all, 2) selective data citation. A rationale for a waiver or bridging of these data falls within this category. • Proposed label for the MUP and/or end use product Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that unregistered source of the active ingredient for another end use product, the active ingredient is considered unregistered. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R334 New	53	New product; MUP or end use product with unregistered source of the active ingredient; requires science data	An application for registration of a new product (MUP or end use product). New manufacturing use product is any product intended (labeled) for formulation or repackaging into an end use formulated pesticide product. The active ingredient is not a new active ingredient, but either (1) one that claims to be substantially similar or identical to another active ingredient which is currently registered (as referenced by EPA registration number) and will use selective data citation, or (2) an end use product which claims to be substantially similar or identical in its formulation to another end use product that is	11	17,993

		review; new physical form; etc. Selective data citation (2) (3)	currently registered for which the selective data citation was used, but the active ingredient used in the formulation is derived from an unregistered source (i.e., does not have a EPA registration number). To fit this category all applications require the following: • A data matrix is required with the application. • Two sets of product specific product chemistry data and CSF's are required: 1) product chemistry (Group A and B) on the unregistered source of the active ingredient and CSF. The applicant must identify to the Agency the toxicity of the impurities associated with the active ingredient ; particularly impurities of toxicological significance (at any level). The impurity profile of the unregistered source of the active ingredient will be compared to registered source. The impurity profile of the unregistered source of the active ingredient either results in new impurities; or impurities of toxicological significance, or if the toxicity of new impurities is unknown to the applicant, then the application is submitted to HED for review . 2) Product chemistry data (Group A and B) for the end use product and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. • Acute toxicity, public health pest efficacy, companion animal safety data and/or child resistant packaging data requirements must be addressed by using: 1) selective data citation. A rationale for a waiver or bridging of these data falls within this category. • Proposed label for the MUP and/or end use product Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that unregistered source of the active ingredient for another end use product, the active ingredient is considered unregistered. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon		

			label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		

			Table 5. Amendments to Registration		
R340	54	Amendment requiring data	Modification in the label, formula, or packaging of a registered product which is substantially similar or is not substantially similar to a currently registered product and which requires the submission of data or	4	3,617

		review within RD (e.g., changes to precautionary label statements) (2) (3)	the citation of data by the registrant which requires an analysis by the Registration Division (RD) only. To fit this category the inert ingredients must already be approved or pending before the Agency for the applicable uses in the product. Examples of actions in this category include: alternate formulations with data including, 5-batch analysis data, label changes to Precautionary Statements based on product chemistry and/or acute product toxicity data; efficacy data; companion animal safety data; child resistant packaging data. Registered source of active ingredient means that the active ingredient has been issued an EPA Registration Number (license). EPA-initiated amendment shall not be charged fees. Label amendments submitted by notification under PR Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees. (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R345 New	55	Amending non-food animal product that includes submission of target animal	Generally modifying an existing, previously registered label by adding additional claims for use on adults or juveniles or breeding animals of the same species. An application to amend a registered end-use pesticide animal product. For example, spot-on products are generally labeled animal specific, in that a product is labeled for dogs or cats, but not generally both, while shampoos and sprays may be labeled for both animals (dogs and	7	8,000

		safety data; previously registered (2) (3)	cats). To fit this category this amendment would require the following: • A data matrix and data compensation forms are required with the application. • All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. In those cases where the product relies upon a pending inert clearance, the new companion animal studies must be conducted with the pending inert in the tested product as it is intended to be marketed and sold as the end use product. • Same species of animal previously listed on registered label. • If new efficacy claims are sought, then new pest efficacy data matching the claim(s) are required. • If the packing type has changed (e.g., spot-on vs. stripe-on) so that the dose volume is altered (new or different), new child resistant packaging data is required. • Which companion animal safety studies are required is based upon the specific label claims in the proposed label. For example, if the proposed end use product label claim is to use the product on 12-week old kittens weighing ≥3 lbs and on breeding cats, then two companion animal studies are required: the first on using kittens ≥ 12 weeks of age and weighing at least 3 lbs. and a second study on pregnant and nursing adult cats. Each of these studies must demonstrate an adequate margin of safety. (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		

R350	56	Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement) (2) (3)	Modification in the label of a registered product that is not substantially similar to a currently registered product and that requires risk analysis by the Agency (i.e. by the Health Effects Division (HED), the Environmental Fate and Effects Division (EFED), the Biological and Economic Analysis Division (BEAD), Alternate Risk Integration Assessment Team(ARIA) etc.) to support the change. Examples of actions in this category include: label changes to Directions for Use (including REI, PPE, PHI, application rate, application frequency, application timing, addition of aerial or chemigation application methods consistent with PR Notice 87-1 and 93-2, ground water or surface water advisory statements, etc. that require risk analysis by EPA. In some cases, the applicant might not submit new data to support the label amendment, but the Agency would need a determination of whether the existing database would support a change or modification to the amended label. EPA-initiated amendment shall not be charged fees. Label amendments submitted by notification under PR Notices, such as and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA 2 fees. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.	9	11,996

R351 New	57	Amendment adding a new unregistered source of active ingredient. (2) (3)	To fit this category all applications require the following: • A data matrix is required with the application. • All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses • If amending an MUP - one set of product specific product chemistry data and CSF is required (under #1 below). • If amending an end-use product then 2 sets of product chemistry data are required . 1) product chemistry (Group A and B) on the unregistered source of the active ingredient and CSF. The applicant must identify to the Agency the toxicity of the impurities associated with the active ingredient ; particularly impurities of toxicological significance (at any level). The impurity profile of the unregistered source of the active ingredient will be compared to registered source. The impurity profile of the unregistered source of the active ingredient either results in new impurities; or impurities of toxicological significance, or if the toxicity of new impurities are unknown to the applicant, then the application is submitted to HED for review . 2) Product chemistry data (Group A and B) for the end use product and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • Acute toxicity, public health pest efficacy and/or child resistant packaging data requirements must be addressed by using: 1) selective data citation. A rationale for a waiver or bridging of these data falls within this category. • Proposed label for the MUP and/or end use product • Table 5: footnotes 2 and 3 apply (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must	8	11,996

			either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R352 New	58	Amendment adding already approved uses; selective method of support; does not apply if the applicant owns all cited data (2) (3)	Modification in the label of a registered end-use or manufacturing product, which is substantially similar or identical to a currently registered product and proposes to add uses to the label that already exist on the label of the substantially similar or identical product identified by the applicant. This category does not require review of new data or bridging of data. Data that are selectively cited to support the amendment must have already been reviewed by the Agency for the same uses, formulation type, active ingredient and claims. Review of efficacy and/or performance data are not included in this category. To fit into this category applications require the following: • A completed data matrix is required identifying the selective method of support. • The application/amendment form must cite the substantial similar or identical product where the uses already exist. • If using the cite-all method of support, the amendment application does not fall into this category, and may be considered as a non-PRIA fast-track submission. (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon	8	11,996

			label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R371	59	Amendment to Experimental Use Permit; (does not include extending a permit's time period (3)	An application to amend an Experimental Use Permit (EUP) application for the currently registered uses. The application requires review of the amendment, including data review and/or new risk assessments for the currently registered uses. If new uses are being proposed, then the application would not fall within this category. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested amendment to the experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.	6	9,151

			Table 6. Other Actions		
R124	60	Conditional Ruling on Pre-application Study Waivers; applicant-initiated	A pre-application request for an active ingredient, new use, or new product. The request is for review of each study waiver associated with any of the above pre-applications. The fee for this category is multiplied by each additional waiver request submitted for review. The study waiver request must include a written rationale for the study waiver and the identity of the new active ingredient (chemical structure). The application follows after the Agency has made a ruling on the study waiver(s). If a study waiver is denied, the application for the new active ingredient, new use or new product can only be	6	2,294

			submitted once the study has been conducted and the applicant has a complete application for registration. The decision on the waiver is conditional upon the review of the formal registration application and the data accompanying the application. Formal decisions or formal feedback on study waivers will not be made in meetings such as pre-registration conferences, Dose Adequacy Response Team meetings (DART), or any other pre-registration meeting with the Agency.		
R272	61	Review of Study Protocol applicant-initiated; **excludes** DART, pre-registration conference, Rapid Response review, DNT protocol review, protocol needing HSRB review	An application for approval of a study protocol. Applicant provides a written copy of the protocol along with any specific questions about the protocol. The fee for this category is multiplied by each additional protocol submitted for review. PRIA fees are not applicable for pre-submission or pre-registration conferences or discussions with the EPA such as Dose Adequacy Response Team (DART), EFED Rapid Response review, ChemSac review, DNT protocol reviews and HSRB review.	3	2,294
R275 New	62	Rebuttal of agency reviewed protocol, applicant initiated	An application or submission to the EPA rebutting the conclusion(s) reached by the EPA for a previously submitted study protocol request. The science review of the study protocol is considered the completed PRIA decision on the protocol review request, so any written response contesting the conclusions in the review is considered to be a separate action and subject to a separate fee under PRIA. This PRIA category applies to rebuttals of all protocol reviews (except HSRB protocol reviews), whether the original protocol was subject to PRIA or not. The fee for this category is multiplied by each rebuttal application that is submitted for review. PRIA fees are not applicable to pre-submission or pre-registration conferences or discussions with the EPA such as Dose Adequacy Response Team (DART), EFED Rapid Response Team, ChemSAC review, and DNT protocol reviews.	3	2,294
R370	63	Cancer reassessment; applicant-initiated	An application which requests to change the cancer classification	18	179,818

Antimicrobials Division					
			Table 7. New Active Ingredients		
A380	64	New Active Ingredient Food use, establish tolerance	An application that proposes a food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The use requires the establishment of an exemption from the requirement of a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), or an increase in an existing tolerance exemption or a food additive regulation	24	104,187

		exemption (2) (3)	or other clearance under section 409 of the FFDCA. The application may need to include a petition to establish an exemption from tolerance for all food commodities covered by the pending registration application(s) or, if residues would not be subject to FFDCA section 408, documentation of an applicable food additive regulation or other clearance under section 409 of the FFDCA. Refer to the definition of a "food use" for the uses subject to this category. All uses (food and non-food) included in any original application or petition for a new active ingredient or a first food use are covered by the base fee for that application in this category if submitted within the original application. Examples include: ▪ Pre- and post-harvest use on crops (other than agricultural fungicides and aquatic herbicides, which are handled as conventional pesticides) ▪ Animal drinking water treatment (meat, meat by-products and/or milk tolerance exemption) ▪ Process water treatment for post harvest use (field washing of raw agricultural commodities) ▪ Treatment of permanent or semi-permanent food contact surfaces (sanitizers and disinfectants) ▪ Use of the product in food contact articles, other than food packaging with an intended ongoing effect in the finished article, including the articles surface or in food that may contact the article (e.g., conveyor belt-claims to kill bacteria on articles that come in contact with belt; or a lubricant with claims that the lubricant kills bacteria ▪ Treatment of raw agricultural commodities in a food processing facility (FDA food additive regulation) ▪ Process water treatment in a food handling facility to control a pest in the water (FDA food additive regulation - EPA dietary risk assessment) ▪ Slimicides (FDA food additive regulation) (e.g., pulp and paper board) ▪ Production of food packaging (FDA food additive regulation)(e.g., adhesives, coatings) ▪ Production of food contact articles other than food packaging (FDA food additive regulation) (cutting board that contains an antimicrobial as a preservative) ▪ Food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment) ▪ Aseptic packaging (FDA food additive regulation) ▪ Ethanol production (treatment of empty fermentation tank) (check with the Agency prior to submission of an application) ▪ Aquatic area application (e.g., lakes, ponds, reservoirs, irrigation systems)(other than aquatic herbicides which are handled as conventional pesticides) ▪ Home produce washes (dietary risk assessment required) ▪ Human drinking water systems (e.g., water purifier units, emergency water systems, municipal water treatment) All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is		

			submitted within the package for the applicable uses. If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A390	65	New Active Ingredient Food use, establish tolerance (2) (3)	An application that proposes a food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The use requires the establishment of or the increase in a tolerance under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA). If residues are reasonably foreseeable or likely to occur in or around food, either directly or indirectly, the application may need to include a petition to establish a tolerance for all food commodities covered by the pending registration application(s). However, some uses may not require a petition but still be considered under this category. Refer to the definition of a "food use" for the uses subject to this category. All uses (food and non-food) included in any original application or petition for a new active ingredient or a first food use are covered by the base fee for that application in this category if submitted	24	173,644

			within the original application. Examples include: ▪ Pre- and post-harvest use on crops (other than agricultural fungicides and aquatic herbicides, which are handled as conventional pesticides) ▪ Animal drinking water treatment (meat, meat by-products, and/or milk tolerance) ▪ Process water treatment for post harvest use (field washing of raw agricultural commodities) ▪ Treatment of permanent or semi-permanent food contact surfaces (sanitizers and disinfectants) ▪ Use in the production of food contact articles, other than food packaging, with an intended ongoing effect in the finished article including the article's surface or in food that may contact the article (e.g. conveyor belt with claims to kill bacteria on articles that come in contact with the belt or a lubricant with claims that the lubricant kills bacteria) ▪ Food handling storage establishments premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment) ▪ Ethanol production (treatment of empty fermentation tank)) (check with the Agency prior to submission of an application) ▪ Aquatic area application (e.g., lakes, ponds, reservoirs, irrigation systems)(other than aquatic herbicides which are handled as conventional pesticides) All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee.		

			The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A400	66	New Active Ingredient, Non-food use, outdoor, FIFRA sec. 2(mm) uses (2) (3)	An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a "food use" as described in the food use categories. Outdoor use means any use that is not indoor as described in the "indoor category" and that fits the definition of an antimicrobial found in FIFRA section 2(mm). All non-food, section 2(mm) uses included in the original application or petition are covered by the base fee for that application in this category if submitted within the original application. Examples include: ▪ Once through cooling tower treatments ▪ Aquatic area application (e.g. sewage/wastewater treatment) other than aquatic herbicides which are handled as conventional pesticides ▪ Industrial processes and water systems treatment (e.g. reverse osmosis water systems, recirculating cooling tower systems, evaporative condensers) ▪ Swimming pools, spas ▪ Oil fields (marine and terrestrial) ▪ Sewage treatment plants (water is treated prior to discharge into the environment) ▪ Wood preservative (2mm use/claims only) Other claims place the product in category A410 ▪ Antifoulant (2mm use/claims only) Other claims place the product in category A410 ▪ Ballast water (2mm use/claims only) Other claims place the product in category A410 All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each	18	86,823

			application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A410	67	New Active Ingredient Non-food use, outdoor, uses other than FIFRA 2(mm) (2) (3)	An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a "food use" as described in the food use categories. Outdoor means any use that is not indoor as described in the "indoor category". Other uses are those uses not covered by the definition of an antimicrobial found in FIFRA section 2(mm). This type of application would be for a product where a claim of pesticidal activity other than or in addition to deterioration caused by bacteria, viruses, fungi, protozoa, algae or slime is made. Examples would include: ▪ Wood preservatives (e.g. termite treatment) ▪ Antifoulants ▪ Ballast water All non-food, section 2(mm) uses included in the original application or petition are covered by the base fee for that application in this category if submitted within the original application. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses.	21	173,644

			A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A420	68	New Active Ingredient Non-food use, indoor, FIFRA sec. 2(mm) uses (2) (3)	An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a "food use" as described in the food use categories. The product is for use inside a manmade structure and fits the definition of an antimicrobial found in FIFRA section 2(mm). All indoor, non-food, section (2mm) uses included in the original application or petition are covered by the base fee for that application in this category if submitted within the original application. Examples include: ▪ Residential use (i.e., carpet sanitizer, hard surface disinfectant) ▪ Commercial, institutional, industrial premise and equipment (e.g. offices, hotels, industrial buildings, nursing homes) ▪ Agricultural premise treatment (e.g., farm structures, buildings and equipment, animal drinking water equipment) ▪ Materials Preservatives (e.g., adhesives, coatings, plastic, fabric) ▪ Industrial processes and water systems treatment (e.g., reverse osmosis water systems, recirculating cooling tower systems, evaporative condensers) ▪ Medical premises and equipment (e.g., dental equipment, dental unit water lines, hospitals)	18	57,882

			▪ HVAC All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A430	69	New Active Ingredient, Non-Food Use Indoor, uses other than FIFRA 2(mm) uses (2) (3)	An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a "food use" as described in the food use categories. The product is for use inside a man made structure. Other uses are those not covered by the definition of an antimicrobial found in FIFRA 2(mm). This type of application would be for a product where a claim of pesticidal activity other than or in addition to deterioration caused by bacteria, viruses, fungi, protozoa, algae or slime is made. All indoor non-food uses included in the original application are covered by the base fee for that application if submitted within the original application. Examples include: ▪ Wood preservative (pressure and non-pressure treatments, e.g., termite treatment for ~~joinery and~~ mill work for door, window frames)	20	86,823

			All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A431	70	New Active Ingredient, Non-food use; indoor; low-risk; low-toxicity food–grade active ingredient(s); efficacy testing for public health claims required under GLP and following DIS/TSS	An application that proposes an indoor non-food use for a low risk/low toxicity food grade active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a "food use" as described in the food use categories. The product is for use inside a manmade structure. Low risk/low toxicity food grade active ingredients are those described in PR Notice 2000-6 (www.epa.gov/PR_Notices/pr2000-6.pdf). Other active ingredients proposed as low risk/low toxicity will be considered on a case–by-case basis. A product making public health claims requires that efficacy data be submitted using a protocol that AD has approved or using a standardized AOAC, ASTM or OECD protocol. DSS/TSS guidance can be found at http://www.epa.gov/oppad001/sciencepolicy.htm. Other protocols that AD has approved are found at http://www.epa.gov/oppad001/regpolicy.htm. All studies must satisfy the GLP regulations. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is	12	60,638

		or AD-approved study protocol (2) (3)	submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		

			Table 8. New Uses		
A440	71	New Use, First Food Use,	An application that proposes the first food use. First food use includes a proposed use for any U.S. registered active ingredient for which there is no registered "food use". The use requires an exemption from the requirement of a tolerance under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) or a food additive regulation or other clearance under section 409 of the FFDCA. If residues	21	28,942

		establish tolerance exemption (2) (3) (4)	are reasonably foreseeable or likely to occur in or around food, either directly or indirectly, and the risks from all foreseeable residues are minimal, the application submission may need to include a petition to establish an exemption from tolerance for all food commodities covered by the pending registration application or if residues would not be subject to FFDCA section 408, documentation of an applicable food additive regulation or other clearance under section 409 of the FFDCA. Refer to the definition of a "food use" for the uses subject to this category. All uses (food and non-food) included in any original application or petition for a first food use and to establish tolerance exemptions are covered by the base fee for that application in this category if submitted within the original application. Examples include: ▪ Pre- and post-harvest use on crops (other than agricultural fungicides and aquatic herbicides, which are handled as conventional pesticides) ▪ Animal drinking water treatment (meat, meat by-products and/or milk tolerance exemption) ▪ Process water treatment for post harvest use (field washing of raw agricultural commodities ▪ Treatment of permanent or semi-permanent food contact surfaces (sanitizers and disinfectants). ▪ Use of the product in food contact articles, other than food packaging with an intended ongoing effect in the finished article, including the articles surface or in food that may contact the article (e.g., conveyor belt - claims to kill bacteria on articles that come in contact with the belt or a lubricant with claims that the lubricant kills bacteria) ▪ Treatment of raw agricultural commodities in a food processing facility (FDA food additive regulation – EPA dietary risk assessment) ▪ Process water treatment in a food handling facility to control a pest in the water (FDA food additive regulation) ▪ Production of food packaging (FDA food additive regulation) (e.g. adhesives, coatings) ▪ Production of food contact articles other than food packaging (FDA food additive regulation) (conveyor belt, cutting board that contains an antimicrobial as a preservative) ▪ Slimicides (FDA food additive regulation) (e.g., pulp and paper board) ▪ Production of food packaging (FDA food additive regulation) (e.g. adhesives, coatings) ▪ Food handling storage establishments premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment) ▪ Aseptic packaging (FDA food additive regulation) ▪ Ethanol production (treatment of empty fermentation tank) (check with the Agency prior to submission of an application) ▪ Aquatic area application (e.g., lakes, ponds, reservoirs, irrigation systems)(other than aquatic herbicides which are handled as conventional pesticides) ▪ Home produce washes (dietary risk assessment required) ▪ Human drinking water systems (e.g., water purifier units, emergency water systems, municipal water treatment) All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is		

			submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A450	72	New use First food use, establish tolerance (2) (3) (4)	An application that proposes the first food use. First food use includes a proposed use of any U.S. registered active ingredient for which there is no registered "food use". The use requires the establishment of an exemption from the requirement of a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), or an increase in or a food additive regulation or other clearance under section 409 of the FFDCA. The application may need to include a petition to establish an exemption from tolerance for all food commodities covered by the pending registration application(s) or, if residues would not be subject to FFDCA section 408, documentation of an applicable food additive regulation or other clearance under section 409 of the FFDCA. Refer to the definition of a "food use" for the uses subject to this category. All uses (food and non-food) included in any original application or	21	86,823

			petition for a first food use are covered by the base fee for that application in this category if submitted within the original application. Examples include: ▪ Pre- and post-harvest use on crops (other than agricultural fungicides and aquatic herbicides, which are handled as conventional pesticides). ▪ Animal drinking water treatment (meat, meat by-products, and/or milk tolerance) ▪ Process water treatment for post harvest use (field washing of raw agricultural commodities) ▪ Treatment of permanent or semi-permanent food contact surfaces (sanitizers and disinfectants). In some cases this will include a disinfectant use ▪ Use in the production of food contact articles, other than food packaging with an intended ongoing effect in the finished article, including the articles surface or in food that may contact the article (e.g., conveyor belt: claims to kill bacteria on articles that come in contact with belt) ▪ Food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment) ▪ Ethanol production (treatment of empty fermentation tank)(check with the Agency prior to the submission of an application) ▪ Aquatic area application (e.g., lakes, ponds, reservoirs, irrigation systems)(other than aquatic herbicides which are handled as conventional pesticides) All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.		

			The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A460	73	New use, additional food use; establish tolerance exemption (3) (4) (5)	An application that proposes an additional food use. Additional food use includes a proposed food use of any U. S. registered active ingredient for which there currently is an approved food use. The use requires the establishment of an exemption from the requirement of a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), or an increase in or a food additive regulation or other clearance under section 409 of the FFDCA. The application may need to include a petition to establish an exemption from tolerance for all food commodities covered by the pending registration application(s) or, if residues would not be subject to FFDCA section 408, documentation of an applicable food additive regulation or other clearance under section 409 of the FFDCA. Refer to the definition of a "food use" for the uses subject to this category. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The fee applies to each additional food use requested in the application. Examples of the uses in this category include: ▪ Pre- and post-harvest use on crops (other than agricultural fungicides and aquatic herbicides, which are handled as conventional pesticides). ▪ Animal drinking water treatment (meat, meat by-products and/or milk tolerance exemption) ▪ Process water treatment for post harvest use (field washing of raw agricultural commodities) ▪ Treatment of permanent or semi-permanent food contact surfaces (sanitizers and disinfectants) ▪ Use in the product of food contact articles, other than food packaging with an intended ongoing effect in the finished article, including the articles surface or in food that may contact the article (conveyor belt - claims to kill bacteria that are on articles that come in contact with belt or a lubricant with claims that the lubricant kills bacteria) ▪ Treatment of raw agricultural commodities in a food processing facility (FDA food additive regulation) ▪ Process water treatment in a food handling facility to control a pest in the water (FDA food additive	15	11,577

			regulation-EPA dietary risk assessment) ▪ Production of food contact articles other than food packaging (FDA food additive regulation) (conveyor belt, cutting board that contains an antimicrobial as a preservative) ▪ Slimicides (FDA food additive regulation) (e.g., pulp and paper board) ▪ Production of food packaging (FDA food additive regulation)(e.g. adhesives, coatings) ▪ Food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment) ▪ Aseptic packaging (FDA food additive regulation) ▪ Ethanol production (treatment of empty fermentation tank) (check with the Agency prior to submission of any application) ▪ Aquatic area application (e.g., lakes, ponds, reservoirs, irrigation systems)(other than aquatic herbicides which are handled as conventional pesticides) ▪ Home produce washes (dietary risk assessment required) ▪ Human drinking water systems (e.g., water purifier units, emergency water systems, municipal water treatment) If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no		

			amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
A470	74	New use, additional food use, establish tolerance (3) (4) (5)	An application that proposes a food use. Additional food use includes a proposed food use of any U. S. registered active ingredient for which there currently is an approved food use. The use requires the establishment of a tolerance, the increase in, or modification of a tolerance under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA). The application may need to include a petition to establish a tolerance for all food commodities covered by the pending application(s). Refer to the definition of a "food use" for the uses subject to this category. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The fee applies to each additional new food use requested in the application. Examples include: ▪ Pre and post harvest use on crops (other than agricultural fungicides and aquatic herbicides, which are handled as conventional pesticides) ▪ Animal drinking water treatment ▪ Process water treatment for post harvest use (field washing of raw agricultural commodities) ▪ Treatment of permanent or semi-permanent food contact surfaces (sanitizers and disinfectants). ▪ Use in the production of food contact articles, other than food packaging with an intended ongoing effect in the finished article, including the articles surface or in food that may contact the article) ▪ Food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment) ▪ Ethanol production (treatment of empty fermentation tank) (check with the Agency prior to submission of an application) ▪ Aquatic area application (e.g., lakes, ponds, reservoirs, irrigation systems)(other than aquatic	15	28,942

			herbicides which are handled as conventional pesticides) If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		

A471 New	75	Additional food uses; establish tolerances; 6 or more submitted in one application (3) (4) (5)	An application that proposes a food use. Additional food use includes a proposed food use of any U. S. registered active ingredient for which there currently is an approved food use. The use may require the establishment of a tolerance, the increase in, or modification of a tolerance under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA). The application may need to include a petition to establish a tolerance for all food commodities covered by the pending application(s). Refer to the definition of a "food use" for the uses subject to this category. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The application must propose at least six (6) or more specific additional new food uses. If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested additional food use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time	15	173,652

			expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
A480	76	New use, Additional use, non-food, outdoor FIFRA sec. 2(mm) uses (4) (5)	An application that proposes a non-food use for an active ingredient with a current EPA registration. A non-food use includes a proposed use that is not a "food use" as described in the food use categories. Outdoor use means any use that is not indoor as described in the "indoor category" and that fits the definition of an antimicrobial found in FIFRA section 2(mm). The fee applies to each new non-food use requested. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. Examples include: ▪ Once through cooling tower ▪ Aquatic area application (other than aquatic herbicides which are handled as conventional pesticides) ▪ Oil fields (marine and terrestrial) ▪ Sewage/wastewater treatment plants (water is treated prior to discharge into the environment) ▪ Swimming pool, spa ▪ Industrial processes and water systems treatment (e.g., reverse osmosis water systems, recirculating cooling tower systems, evaporative condensers) ▪ Any of the above use patterns that would result in a significant increase in the level of exposure (increase in dosage rate, or a change in the route of exposure (fog vs. spray) to the active ingredient for man or other organisms ▪ Wood preservative (2mm use/claims only) Other claims, place the product in category A490) ▪ Antifoulants (2mm use/claims only) Other claims, place the product in category A490) ▪ Ballast water (2mm use/claims only) Other claims, place the product in category A490) All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant	9	17,365

			the requested new use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
A481 New	77	Additional non-food outdoor uses; FIFRA §2(mm) uses; 6 or more submitted in one application (4) (5)	An application that proposes a non-food use for an active ingredient with a current EPA registration. The fee applies to each non-food use in this category requested in the application. A non-food use includes a proposed use that is not a “food use” as described in the food use categories. Outdoor use means any use that is not indoor as described in the “indoor category” and that fits the definition of an antimicrobial found in FIFRA section 2(mm). The fee applies to each new non-food use requested. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The application must propose at least six (6) or more specific new additional non-food uses. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.	9	104,190

			The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
A490	78	New use, additional use, non-food, outdoor, uses other than FIFRA 2(mm) (4) (5)	An application that proposes a non-food use for an active ingredient with a current EPA registration. The fee applies to each non-food use in this category requested in the application. A non-food use includes a proposed use that is not a “food use” as described in the food use categories. Outdoor means any use that is not indoor as described in the “indoor category”. Other uses are those uses not covered by the definition of an antimicrobial found in FIFRA section 2(mm). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. This type of application would be for a product where a claim of pesticidal activity other than or in addition to deterioration caused by bacteria, viruses,	15	28,942

			fungi, protozoa, algae or slime is made. Examples would include: ▪ Wood preservatives (e.g. termite claim) ▪ Antifoulants ▪ Ballast water ▪ Any of the above use patterns that would result in a significant increase in the level of exposure (increase in dosage rate, or a change in the route of exposure (fog vs. spray), to the active ingredient of man or other organisms. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application.		

			Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
A491 New	79	Additional non-food; outdoor; uses other than FIFRA §2(mm); 6 or more submitted in one application (4) (5)	An application that proposes a non-food use for an active ingredient with a current EPA registration. A non-food use includes a proposed use that is not a "food use" as described in the food use categories. Outdoor means any use that is not indoor as described in the "indoor category". Other uses are those uses not covered by the definition of an antimicrobial found in FIFRA section 2(mm). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The application must propose at least six (6) or more specific new additional non-food outdoor uses. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s)	15	173,652

			application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
A500	80	New use, additional use, non-food, indoor FIFRA sec. 2(mm) uses (4) (5)	An application that proposes a non-food use for an active ingredient with a current EPA registration. The fee applies to each non-food use in this category requested in the application. A non-food use includes a proposed use that is not a "food use" as described in the food use categories. The product is for use inside a manmade structure or is a low exposure use pattern that requires minimal ecological and/or environmental fate data (see examples below) and that fits the definition of an antimicrobial found in FIFRA section 2(mm). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. Examples include: ▪ Residential use (i.e., carpet sanitizer, hard surface disinfectant) ▪ Commercial, institutional, industrial premise and equipment (e.g. offices, hotels, industrial buildings, nursing homes) ▪ Agricultural premise treatment (e.g., farm structures, buildings and equipment, animal drinking water equipment) ▪ Materials Preservatives (e.g., adhesives, coatings, plastic, fabric) ▪ Industrial processes and water systems treatment (e.g., reverse osmosis water systems, re-circulating cooling tower systems, evaporative condensers) ▪ Medical premises and equipment (e.g., dental equipment, dental unit water lines, hospitals) ▪ HVAC ▪ Any of the above use patterns that would result in a significant increase in the level of exposure (increase in dosage rate, or a change in the route of exposure (fog vs. spray), to the active ingredient of man or other organisms. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must	9	11,577

			either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
A501 New	81	Additional non-food; indoor; FIFRA §2(mm) uses; 6 or more submitted in one application (4) (5)	An application that proposes a non-food use for an active ingredient with a current EPA registration. A non-food use includes a proposed use that is not a "food use" as described in the food use categories. The product is for use inside a manmade structure or is a low exposure use pattern that requires minimal ecological and/or environmental fate data (see examples below) and that fits the definition of an antimicrobial found in FIFRA section 2(mm). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The application must propose at least six (6) or more specific new additional non-food indoor uses. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency	9	69,462

			will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
A510	82	New use, additional use, non-food, indoor, other than FIFRA 2(mm) uses (4) (5)	An application that proposes a non-food use for an active ingredient with a current EPA registration. The fee applies to each non-food use in this category requested in the application. A non-food use includes a proposed use that is not a “food use” as described in the food use categories. The product is for use inside a manmade structure. Other uses are those uses not covered by the definition of an antimicrobial found in FIFRA 2(mm). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. Examples include: ▪ Wood preservative, pressure and non-pressure treatments (e.g., joinery and mill work for door, window frames) ▪ Any significant increase in exposure requiring science review (increase in dosage rate, different	12	11,577

			method of application (fog vs. spray) will be treated as a new use All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
A511 New	83	Additional non-food; indoor; uses other than FIFRA §2(mm); 6 or more	An application that proposes a non-food use for an active ingredient with a current EPA registration. A non-food use includes a proposed use that is not a “food use” as described in the food use categories. The product is for use inside a manmade structure. Other uses are those uses not covered by the definition of an antimicrobial found in FIFRA 2(mm). A different pattern of use that significantly changes	12	69,462

		submitted in one application (4) (5)	or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The application must propose at least six (6) or more specific new additional non-food indoor uses. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		

			Table 9. New Products and Amendments		
A530	84	New product, identical or substantially similar in composition and use to a registered product; no data review or only product chemistry	An application for registration of an end-use or a manufacturing use pesticide product that is substantially similar, identical in its uses and formulation or that differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment to products that are currently registered. The applicant must identify the similar products for all active ingredients in the proposed product. All applications require the following: ▪ A data matrix is required with the application if it is not a 100% re-packaged product. ▪ Product chemistry data (Group A and B) unless the product is identical (e.g. 100% repackaged product). ▪ The active ingredient listed on the CSF must be an EPA registered product.	4	1,159

		data; cite all data citation or selective data citation where applicant owns all required data; or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing use product that requires no data submission nor data matrix. (2) (3)	▪ In all cases, the registrant must identify the registered similar product for this category. ▪ Acute toxicity requirements must be addressed by using: 1) the cite-all method 2) selective data citation where the applicant owns all required data, or 3) applicant submits specific authorization letter from the data owner. The application is not in this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category. If the use pattern on the TGAI differs from the proposed products, then additional data are required and the application does not fall within this category. **Substantially similar:** Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the product bears the same use patterns or fewer. Adding to or changing existing use patterns excludes the product from treatment as a substantially similar product. Substantially similar use patterns for public health products are limited to identical organisms on both products. For non-public health products substantially similar use patterns are limited to identical organisms on both products. Deleting use patterns is acceptable **Identical products**: Same composition and use patterns as an already registered end-use product. **Manufacturing Use Product**: A 100% re-package of a manufacturing use product that requires neither data submission nor data matrix is covered by this category. **Unregistered:** The Agency has not issued an EPA Registration Number (license) for the source material. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency		

			will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A531	85	New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where the applicant does not own all required data and does not have a specific authorization letter from data owner. (2) (3)	An application for registration of an end-use pesticide product that is substantially similar or identical in its uses and/or formulation to products that are currently registered or differ only in ways that would not significantly increase the risk of unreasonable adverse effects. The applicant must identify the similar products for all active ingredients in the proposed product. All applications require the following: ▪ A data matrix is required with the application. ▪ Product chemistry data (Group A and B) unless the product is identical. In some cases product chemistry data can be satisfied as outlined in PR Notice 98-1. ▪ All inert ingredients must be already approved for the applicable uses in the product. ▪ The source of the active ingredient must be currently registered (licensed) with the Agency. ▪ In all cases, the applicant must identify the currently registered similar product for this category. ▪ Acute toxicity, efficacy, public health pest efficacy, and/or child resistant packaging data requirement must be addressed by using: 1) the cite-all method, or 2) selective data citation where the applicant does not own all required data and does not have a specific authorization letter from the data owner. If a review of data other than product chemistry is needed, the application does not fall into this category. The application does not fall into this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category. If the use pattern on the TGAI differs from the proposed products, then additional data are required and the application does not fall within this category. **Substantially similar:** Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular) and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the proposed product	4	1,654

			bears the same use patterns. Adding to or changing existing use patterns excludes the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable. **Identical:** Same composition and use patterns as a currently registered end use product. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A532	86	New product; identical or substantially similar in composition and use to a registered product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted. (2) (3)	An application for registration of an end-use pesticide or manufacturing use product that uses an unregistered source of the active ingredient and that is substantially similar or identical in its uses and/or formulation to products that are currently registered or differ only in ways that would not significantly increase the risk of unreasonable adverse effects. All applications require the following: ▪ Product chemistry data (Group A and B) on the end-use product as well as the unregistered source of active ingredient. ▪ The cite-all method must be used to satisfy the generic data requirements. ▪ Acute toxicity requirements must be addressed by using the cite-all method. ▪ In all cases, the applicant must identify the currently registered similar product for this category. The application is not this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category. If the use pattern on the TGAI differs from the proposed product, then additional data are	5	4,631

			required and the application does not fall within this category. **Substantially similar:** Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular) and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the proposed product bears the same use patterns. Adding to or changing existing use patterns excludes the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable. **Identical:** Same composition and use patterns as a currently registered end use product. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A540	87	New end use product; FIFRA § 2(mm) uses only (2) (3)	An application for registration of a pesticide product that is not substantially similar or identical in its uses or formulation to products that are currently registered. All applications require the following: ▪ A data matrix is required with the application. ▪ Product chemistry data (Group A and B) unless the product is identical. In some cases product chemistry data can be satisfied as outlined in PR Notice 98-1. ▪ All inert ingredients must be already approved or pending with the Agency for the applicable uses in the product. ▪ Acute toxicity, efficacy, public health pest efficacy, companion animal safety data and/or child resistant packaging data requirements must be addressed by using : 1) the cite-all method, or 2) selective data citation which includes submitting the required data. A rationale for a waiver of these data falls within this category.	5	4,631

			▪ For a wood preservative, antifoulant or ballast water treatment product, a claim that differs from those described in FIFRA 2mm will place the product in the A550 category. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A550	88	New end use product, uses other than FIFRA sec. 2(mm); non-FQPA product (2) (3)	An application for registration of a pesticide product that is not substantially similar or identical in its uses or formulation to products that are currently registered. These applications require product chemistry data (Group A and Group B), acute toxicity data (addressing all 6 endpoints), and possibly leaching data. This type of application would be for a product where a claim of pesticidal activity other than or in addition to deterioration caused by bacteria, viruses, fungi, protozoa, algae or slime is made. Examples would include: ▪ Wood preservatives (e.g., termite claim) ▪ Antifoulants ▪ Ballast water ▪ Any of the above use patterns that would result in a significant increase in the level of exposure (increase in dosage rate, or a change in the route of exposure (fog vs. spray), to the active ingredient of man or other organisms. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new	7	4,631

			product with an unregistered source of active ingredient. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A560	89	New manufacturing use product, registered active ingredient, selective data citation (2) (3)	An application for registration of a manufacturing use pesticide product that is substantially similar or identical in its formulation to products that are currently registered. New Manufacturing use product is any product intended (labeled) for formulation or repackaging into an end use formulated pesticide product. This product does not contain directions for use of the product as distributed or sold, or after combination by the user with other substances. All applications require the following: ▪ A data matrix is required with the application. ▪ Product chemistry data (Group A and B) are required. In some cases, product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. ▪ All inert ingredients must be approved for the applicable uses in the product. An application proposed as a 100% re-packaged product does not fall within this category. An application for registration of a new product that is a salt of an already registered active ingredient where there are not any currently registered products for this salt. The Agency will decide on a case-by-case basis whether an ingredient should be classified as a new active ingredient. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new	12	17,365

			product with an unregistered source of active ingredient. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A570	90	Label Amendment requiring data review (3) (4)	An application for amended registration which requires review of data. This includes chemistry, toxicology, efficacy or other science review. Examples include: ▪ Any submission that includes efficacy data or that requires an efficacy review. ▪ Signal word changes/review of acute toxicity data ▪ New active ingredient (ai) sources - change from one unregistered source to another or change from a registered source to an unregistered source ▪ Any submission requesting a CRP exemption ▪ Any formula change that requires efficacy data, including confirmatory data. Routine formula changes are not PRIA actions. Routine formula changes are those which do not require data to support the change such as a new fragrance, dye or other addition or modification to the inert ingredients in the formula. ▪ Antifoulant product formula changes which require a release rate study to be submitted ▪ Any application that is significantly inconsistent with an applicable RED. For example, disagreement with a batching designation. **NOTE:** Any significant increase in exposure requiring science review (increase in dosage rate, different method of application (fog vs. spray) will be treated as a new use. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested label amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the	4	3,474

			applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.		
A572 New	91	New Product or amendment requiring data review for risk assessment by Science Branch (e.g., changes to REI, or PPE, or use rate) (2) (3) (4)	An application for registration of a pesticide product that is not substantially similar or identical in its uses or formulation to products that are currently registered OR a modification in the label of a registered product that is not substantially similar or identical in its uses to a currently registered product; that requires risk analysis by the Science Branches (i.e. by the Risk Assessment and Science Support Branch (RASSB), Product Science Branch (PSB), etc.) to support the change. Examples of actions in this category include: label changes to Directions for Use (including REI, PPE, PHI, application rate, application frequency, application timing, increase in dosage rate, different method of application (fog vs. spray), exposure change, etc. that require risk analysis by EPA. In some cases, the applicant might not submit new data to support the label amendment, but the Agency would need a determination of whether the existing database would support a change or modification to the amended label. EPA-initiated amendment shall not be charged fees. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant	9	11,996

			the requested new product/amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.		

			Table 10. Experimental Use Permits and Other Type of Actions		
A520	92	Experimental Use Permit application (2)	An experimental use permit is a tool that allows an unregistered pesticide to be used, or a registered pesticide to be used for an off-label use, under controlled, field or actual use conditions so that data required to support a FIFRA section 3 registration can be developed (e.g., data necessary to evaluate efficacy and potential for safe use or adverse effects on humans and the environment such as a swimming pool use). If residues are reasonably foreseeable or likely to occur, the application submission must contain one of the following: (i) evidence of applicable FFDCA tolerances, exemptions, or	9	5,789

			clearances; (ii) a petition to establish a tolerance(s) or exemption(s) for all food commodities; (iii) certification that all food or feed derived from the experimental use will be destroyed, fed only to experimental animals for testing purposes, or disposed of in a manner that precludes its consumption as food or feed and presents no unreasonable adverse effects on the environment. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A521	93	Review of public health efficacy study protocol within AD; per AD Internal Guidance for the Efficacy Protocol Review Process; Code will also include review of public health efficacy study protocol and data review for devices making pesticidal claims; Applicant initiated; Tier 1	An application that requires the review of a modified protocol where only minor changes are made to an existing efficacy method (e.g. AOAC International, ASTM, AATCC, or an AD approved method described in A431). The study design for a Tier 1 protocol will be reviewed and approved within AD. A draft label with proposed directions for use and use claims must accompany the application. Examples of minor changes include: varied test conditions (e.g., contact time, use of different hard surface carrier types [porcelain penicylinders vs. stainless steel penicylinders], modification of standard method to support additional microorganisms [e.g., Germicidal Spray Products test for spore-formers], and changes to support alternate application types [e.g., foams]. A pre-registration meeting is recommended prior to submission of the protocol. The Agency will make every effort during this meeting to determine if the protocol is Tier 1. If during further review, the Agency determines that a Tier l protocol should be elevated to Tier 2 status, the applicant will receive notification prior to this change. Protocol review and approval must be completed before efficacy data is generated using the approved protocol and an application for registration is submitted to AD.	3	2,250

A522	94	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; Code will also include review of public health efficacy study protocol and data review for devices making pesticidal claims; Applicant initiated; Tier 2	An application that requires the review of a new public health efficacy protocol, or a major change to an existing efficacy method (e.g. AOAC International, ASTM, AATCC, or an AD approved method described in A431). Applies to a study design that requires review by external members of an AD Efficacy Protocol Review Expert Panel. A draft label with proposed directions for use and use claims must accompany the application, along with proposed performance measures. Examples of major protocol changes would include surrogate consideration, field test component, air sanitizers, simulated or in-use testing, changes in growth conditions [e.g., shaking vs. static for TB testing] and novel protocols for products with label claims that don't meet the recommended, conventional sterilant/disinfectant/sanitizer standards (e.g., treated materials). A pre-registration meeting is recommended prior to submission of the protocol. The Agency will make every effort during this meeting to determine if the protocol is Tier 2. Protocol review and approval must be completed before efficacy data is generated using the approved protocol and an application for registration is submitted to AD.	12	11,025
A524 New	95	New Active Ingredient, Experimental Use Permit application; Food Use Requires Tolerance. Credit 45% of fee toward new active ingredient application that follows. (2)	An Experimental Use Permit (EUP) application for food use(s) of an active ingredient that is not contained as an active ingredient in any currently U.S. registered pesticide product. The application proposes a food use. The use may require the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted simultaneously. A credit of 45% of the New Active Ingredient fee will be applied to the application that follows. Examples such as: ▪ Pre- and post-harvest use on crops (other than agricultural fungicides and aquatic herbicides, which are handled as conventional pesticides) ▪ Animal drinking water treatment (meat, meat by-products, and/or milk tolerance) ▪ Process water treatment for post harvest use (field washing of raw agricultural commodities) ▪ Treatment of permanent or semi-permanent food contact surfaces (sanitizers and disinfectants) Note: See A390 for additional examples.	18	138,916

			All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A525 New	96	New Active Ingredient, Experimental Use Permit application; Food Use Requires Tolerance Exemption. Credit 45% of fee toward new active ingredient application that follows. (2)	An Experimental Use Permit (EUP) application for food use(s) of an active ingredient that is not contained as an active ingredient in any currently U.S. registered pesticide product. The application proposes a food use. The use may require the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted simultaneously. A credit of 45% of the New Active Ingredient fee will be applied to the application that follows. Examples such as: Pre- and post-harvest use on crops (other than agricultural fungicides and aquatic herbicides, which are handled as conventional pesticides) • Animal drinking water treatment (meat, meat by-products and/or milk tolerance exemption) • Process water treatment for post harvest use (field washing of raw agricultural commodities) • Treatment of permanent or semi-permanent food contact surfaces (sanitizers and disinfectants) Note: See A380 for additional examples All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.	18	83,594

			The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A526 New	97	New Active Ingredient, Experimental Use Permit application; Non-Food, Outdoor Use. Credit 45% of fee toward new active ingredient application that follows. (2)	An Experimental Use Permit (EUP) application for non-food use(s) of an active ingredient that is not contained as an active ingredient in any currently U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not indoor as described in the indoor category. All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. . A credit of 45% of the New Active Ingredient fee will be applied to the application that follows. A credit of 45% of the New Active Ingredient fee will be applied to the application that follows. Examples of Non-food outdoor uses could include: ▪ Aquatic area application (e.g., sewage/wastewater treatment)(other than aquatic herbicides which are handled as conventional pesticides) ▪ Oil fields (marine and terrestrial) ▪ Sewage treatment plants (water is treated prior to discharge into the environment) ▪ Wood preservatives ▪ Antifoulants ▪ Ballast water ▪ Industrial processes and water systems treatment All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting	15	86,823

			documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A527 New	98	New Active Ingredient, Experimental Use Permit application; Non-Food, Indoor Use. Credit 45% of fee toward new active ingredient application that follows. (2)	An Experimental Use Permit (EUP) application for non-food use(s) of an active ingredient that is not contained as an active ingredient in any currently U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Indoor means that the proposed use is for use inside of manmade structures. All indoor non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. A credit of 45% of the New Active Ingredient fee will be applied to the application that follows. Examples include: ▪ Residential use (i.e., carpet sanitizer, hard surface disinfectant) ▪ Commercial, institutional, industrial premise and equipment (e.g. offices, hotels, industrial buildings, nursing homes) ▪ Agricultural premise treatment (e.g., farm structures, buildings and equipment, animal drinking water equipment) ▪ Materials Preservatives (e.g., adhesives, coatings, plastic, fabric) ▪ Medical premises and equipment (e.g., dental equipment, dental unit water lines, hospitals) ▪ HVAC All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.	15	58,000

A528 New	99	Experimental Use Permit application, Food Use; Requires Tolerance or Tolerance Exemption (2)	Experimental Use Permit (EUP) application for a new food use(s) for any U. S. registered active ingredient that is currently not registered for the proposed use. The use requires the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). Increases in exposure such as a dosage rate increase or different method of application that will result in a temporary tolerance increase belong to this category. Examples of food uses could include: ▪ Pre- and post-harvest use on crops (other than agricultural fungicides and aquatic herbicides, which are handled as conventional pesticides). ▪ Animal drinking water treatment (meat, meat by-products and/or milk tolerance exemption) ▪ Process water treatment for post harvest use (field washing of raw agricultural commodities) ▪ Treatment of permanent or semi-permanent food contact surfaces (sanitizers and disinfectants) ▪ Use in the production of food contact articles, other than food packaging with an intended ongoing effect in the finished article, including the articles surface or in food that may contact the article (conveyor belt - claims to kill bacteria that are on articles that come in contact with belt or a lubricant with claims that the lubricant kills bacteria) ▪ Treatment of raw agricultural commodities in a food processing facility (FDA food additive regulation) ▪ Process water treatment in a food handling facility to control a pest in the water (FDA food additive regulation-EPA dietary risk assessment) All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.	15	20,260
A529	100	Amendment to Experimental Use	An application to amend an Experimental Use Permit (EUP) application for the currently registered uses. The application requires review of the amendment, including data review and/or new risk assessments	9	10,365

New		Permit; requires data review or risk assessment (2)	for the currently registered uses. If new uses are being proposed, then the application would not fall within this category. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A523 New	101	Review of protocol other than a public health efficacy study (i.e., Toxicology or Exposure Protocols)	An application for approval of each study protocol submitted other than for public health studies. Applicant provides a written copy of the protocol along with any specific questions about the protocol. The fee for this category is multiplied by each additional protocol submitted for review.	9	11,025
A571 New	102	Science reassessment: Cancer risk, refined ecological risk, and/or endangered species; applicant-initiated	An application in which a request is made to change or refine the cancer classification or ecological risk; applicant initiated.	18	86,823

Biopesticides and Pollution Prevention Division					
			Table 11. Microbial and Biochemical Pesticides; New Active Ingredients		
B580	103	New active ingredient; food use; establish tolerance (2)	**An application that proposes a food use for a microbial or biochemical pesticide active ingredient that is not currently an active ingredient in any U.S. registered pesticide product. The use requires the establishment of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish a tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted within the original application.** . Examples of food uses include: use on foods, for example, corn or apples; aquatic	19	46,305

			uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee.		
B590	104	New active ingredient; food use; petition to establish tolerance exemption (2)	**An application that proposes a food use for a microbial or biochemical pesticide active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The use requires the establishment of a tolerance exemption under section 408 of the FFDCA. The application submission must contain a petition to establish a tolerance exemption for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted within the original application.** Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be	17	28,942

			subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee.		
B600	105	New active ingredient; non-food use (2)	**An application that proposes a non food use for a microbial or biochemical pesticide active ingredient that is not currently an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not indoor and could include treatment of ornamentals in a shade house and turf uses. Indoor means that the proposed use is for use inside of manmade structures. All indoor non-food uses included in the application are covered by the base fee for the application in this category if submitted within the original application. Some examples of indoor uses are termiticide structural protection, and indoor residential treatments (i.e. cockroach treatments). All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously.** All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee.	13	17,365
B610	106	New active ingredient; Experimental Use Permit application; petition to establish temporary tolerance or temporary tolerance exemption	**An Experimental Use Permit (EUP) application where the proposed use meets the definition of a food use. The use requires the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish temporary tolerances or exemption from tolerances for all food/feed commodities covered by the pending registration application(s). Increases in exposure such as a dosage rate increase or different method of application that will result in a temporary tolerance increase belong to this category.** . Examples of food uses include: use on foods, for	10	11,577

			example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. **The Agency will not accept a certification for crop destruct once the review clock has started (the "clock" or decision review timeframe starts 21 days after the Agency receives the application and the required fees or approves a fee waiver or fee exemption). A change to a crop destruct application would require the applicant to withdraw their application and start the application process anew.** All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses		
B611 New	107	New active ingredient; Experimental Use Permit application; petition to establish permanent tolerance exemption	**An Experimental Use Permit (EUP) application for a microbial or biochemical pesticide product containing an active ingredient that is not an active ingredient in any currently U.S. registered pesticide product. The application proposes a food use. The use requires the establishment of an exemption from the requirement of a tolerance under section 408 of the FFDCA. The application must contain a petition to establish an exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s).** . Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. **The Agency will not accept a certification for crop destruct once the review clock has started. A change to a crop destruct application would require the applicant to withdraw their application and start the application process anew.** All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses	12	11,577
B612 New	108	New active ingredient; no change to a permanent tolerance exemption (2)	**An application that proposes a food use for a microbial or biochemical pesticide active ingredient that is not currently an active ingredient in any U.S. registered pesticide product. The use does not require the establishment/amendment of a tolerance exemption under section 408 of the FFDCA. The application contains uses for food/feed commodities that are all currently covered by an existing tolerance or tolerance exemption. All uses (food and non-food) included in any original application or petition for a new active ingredient are**	10	15,918

			covered by the base fee for the application in this category if submitted within the original application. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee.		
B613 New	109	New active ingredient; petition to convert a temporary tolerance or a temporary tolerance exemption to a permanent tolerance or tolerance exemption (2)	**An application that proposes a food use for a microbial or biochemical pesticide active ingredient that is not currently an active ingredient in any U.S. registered pesticide product. The use requires the conversion of an existing temporary/tolerance or exemption to a permanent tolerance under section 408 of the FFDCA. The application contains uses for food/feed commodities that are all currently covered by an existing tolerance or tolerance exemption and must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The petition will not contain new data for review in this category. The agency will assess the risks associated with the conversion of the commodities. If conversion of a crop group or subgroup or commodities requires submission of new data, the action does not belong in this category. The appropriate category will be one of the food use categories (e.g.B580).** **All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted within the original application.** Examples of food uses include: use on foods, for example, corn or	11	15,918

			apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee.		
B620	110	New active ingredient; Experimental Use Permit application; Non-Food Use including crop destruct;	An application for an Experimental Use Permit for a microbial or biochemical pesticide, with uses that do not fall under the definition of a food use, or with an agreement to destroy or use only for experimental purposes any crops treated during the experimental program. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.	7	5,789

			Table 12. Microbial & Biochemical New Uses		
B630	111	First food use; petition to	An application for registration of a new use for a microbial or biochemical pesticide, where the	13	11,577

		establish tolerance exemption (2)	proposed first food use meets the definition of a food use, requires that the applicant submit data to enable the Agency to conduct a dietary exposure assessment and requires that the applicant submit a petition for an exemption from the requirement of a tolerance for the active ingredient. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee.		
B631	112	New food use; petition to amend an established tolerance (3)	A petition to amend an existing tolerance exemption for a microbial or biochemical pesticide active ingredient where the proposed use meets the definition of a food use and requires that the applicant submit data to enable the Agency to conduct a dietary exposure assessment and that the applicant submit a petition for an exemption from the requirement of a tolerance for the active ingredient. This category includes amendments to temporary tolerance exemptions and other time-limited tolerance exemptions. In addition to the petition, there may be an application to amend an existing registered product or experimental use permit. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception is if the new use(s) are to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more	12	11,577

			after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
B640	113	First food use; petition to establish tolerance (2)	An application for registration of a new use for a microbial or biochemical pesticide where there is a reasonable expectation or certainty that residues of the active ingredient could occur in human food, animal feed, or in livestock from the proposed use. The first food use requires the applicant to submit a petition to establish a tolerance for the active ingredient for the proposed use, and to submit data to demonstrate that dietary exposures to residues of the active ingredient at the tolerance level meet the FFDCA standard of reasonable certainty of no harm. All uses included in any original application or petition for a first food use that otherwise satisfy the conditions for the category are covered by the base fee for that application. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee.	19	17,365
B643 New	114	New Food use; petition to amend tolerance exemption (3)	**An application that proposes a new/additional food use for a microbial or biochemical pesticide active ingredient. New/additional food use includes a proposed use of any U. S. registered active ingredient for which there is no registered "food use". The use requires the amendment of the existing exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to amend tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s).** All of the inerts used in the product must be either approved or pending with the Agency for the applicable	10	11,577

			uses. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception is if the new use(s) are to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		
B642 New	115	First food use; indoor; food/food handling (2)	**An application for a microbial or biochemical pesticide that proposes the first indoor, food/food handling use. First food use includes a proposed use of any U. S. registered active ingredient for which there is no registered "food use." The use requires the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemptions from tolerance for all food/feed commodities covered by the pending registration application(s). Indoor means that the proposed use is for use inside of manmade structures. All indoor food uses included in any original application or petition for the first food use are covered by the base fee for the application in this category if submitted within the original application.** Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses.	12	28,942

			A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee.		
B644 New	116	New use, no change to an established tolerance or tolerance exemption (3)	**An application that proposes a new use for a microbial or biochemical pesticide active ingredient. New use (indoor/outdoor/food handling) includes a proposed use of any U.S. registered active ingredient for which there is no registered use. The use does not require an amendment to the established tolerance or tolerance exemption under section 408 of the FFDCA. The application contains uses for food/feed commodities that are all currently covered by an existing tolerance or tolerance exemption.** All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception is if the new use(s) are to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.	8	11,577

B650	117	New use; non-food (3)	An application for registration of a new use for a microbial or biochemical pesticide, with uses that do not fall under the definition of a food use. This category also includes a change in use pattern such that the exposure to humans and the environment could be significantly increased (e.g., additional routes of exposure) and therefore must be evaluated for increased risks. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. Any other information not requested or required by the Agency, that is submitted by the applicant to support the new use(s) application, which is received 21 days or more after the original application, will be assessed 25% of the full registration service fee for the new use(s) application. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.	7	5,789

			Table 13. Microbial and Biochemical New Products		

B652 New	118	New product; registered source of active ingredient; requires petition to amend established tolerance or tolerance exemption; requires 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply (2)	**An application for registration of a microbial or biochemical pesticide product that is not substantially similar or identical in its uses and formulation to a product currently registered. The use requires the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s).** All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. **An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient.**	13	11,577
B660	119	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption; no data review or only product chemistry data; cite-all data citation, or selective data citation where applicant owns	An application for registration of an end-use or a manufacturing use microbial or biochemical pesticide product that is substantially similar, identical in its uses and formulation, or that differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment to products that are currently registered. The applicant must identify the similar registered products for all active ingredients in the proposed product. All applications require the following: • A data matrix is required with the application if it is not a 100% re-packaged product. • Product chemistry data (Group A and B) unless the product is identical (e.g., 100% repackaged product). In some cases, product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • The active ingredient(s) must be currently registered and the CSF must include its EPA	4	1,159

		all required data, or authorization from data owner is demonstrated. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission or data matrix. For microbial pesticides, the active ingredient(s) must not be re-isolated. (2)	Registration Number(s). • In all cases, the registrant must identify the registered similar product for this category. • Acute toxicity requirements must be addressed by using: 1) The cite-all method 2) Selective data citation where the applicant owns all required data, or 3) Applicant submits specific authorization letter from the data owner The application is not in this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does **not** belong in this fee category. If the use pattern on the TGAI differs from the proposed products, then additional data are required and the application does not fall within this category. **Substantially similar:** Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the proposed product bears the same use pattern. Adding to or changing existing use patterns excludes the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable. **Identical:** Same composition and use patterns as a currently registered end-use product. **Manufacturing Use Product:** A 100% re-package of a manufacturing use product that requires no data submission or data matrix is covered by this category. **An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient.**		
B670	120	New product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption; requires 1) submission of product specific	An application for registration of a microbial or biochemical pesticide product that is **not** substantially similar or identical in its uses and/or formulation to products that are currently registered. These applications require product specific chemistry data, acute toxicity data and other Tier I mammalian and non-target toxicity data as determined by the general use patterns for the product. When public health pests are claimed, efficacy (product performance) data for the product must be submitted. Formulator's exemption for the data requirements can be claimed when the source of the TGAI is	7	4,631

		data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply (2)	registered by another pesticide registrant. If the registered source of the active ingredient is owned by the current applicant, Formulator's exemption is not applicable. The data used to support the registered source is instead referenced on the applicant's data matrix. This category is not for a new use. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. **An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient.**		
B671	121	New product; food use; unregistered source of active ingredient(s); requires a petition to amend an established tolerance or tolerance exemption; requires 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data	An application for registration of a microbial or biochemical pesticide product that is **not** substantially similar or identical in its uses and/or formulation to products that are currently registered. These applications require product specific chemistry data, acute toxicity data and other Tier I mammalian and non-target toxicity data as determined by the general use patterns for the product. When public health pests are claimed, efficacy (product performance) data for the product must be submitted. This category includes products containing an active ingredient(s) that requires a change in, or establishment of, a tolerance or tolerance exemption, and in those situations there must be a petition to establish or amend an existing tolerance or tolerance exemption for the active ingredient. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. **An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient.**	17	11,577

		requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply (2)			
B672	122	New product; unregistered source of active ingredient(s); non-food use or food use with a tolerance or tolerance exemption previously established for the active ingredient(s); requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (2)	An application for registration of a microbial or biochemical pesticide product that is **not** substantially similar or identical in its uses and/or formulation to products that are currently registered. These applications require product specific chemistry data, acute toxicity data and other Tier I mammalian and non-target toxicity data as determined by the general use patterns for the product. When public health pests are claimed, efficacy (product performance) data for the product must be submitted. This category does not include products containing an active ingredient(s) that requires a change in, or establishment of, a tolerance or tolerance exemption or require the Agency to conduct a dietary risk assessment. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. **An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient.**	13	8,269

B673 New	123	New product MUP/EP; unregistered source of active ingredient(s); citation of Technical Grade Active Ingredient (TGAI) data previously reviewed and accepted by the Agency. Requires an Agency determination that the cited data supports the new product. (2)	**An application for registration of a new microbial or biochemical pesticide product (MUP or end use product). New manufacturing use product is any product intended (labeled) for formulation or repackaging into an end use formulated pesticide product. The active ingredient is not a new active ingredient, but one that claims to be substantially similar or identical to another active ingredient which is currently registered (as referenced by EPA registration number) and has the selective data citation used. Or an end use product which claims to be substantially similar or identical in its formulation to another end use product that is currently registered for which the selective data citation was used, but the active ingredient used in the formulation is derived from an unregistered source (i.e., does not have a EPA registration number).** All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. **An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient.**	10	4,631
B674 New	124	New product MUP; Repack of identical registered end-use product as a manufacturing-use product; same registered uses only (2)	**An application for registration of a new microbial or biochemical pesticide manufacturing use product that is identical in its formulation and uses to end use products that are currently registered. All applications require the following:** • **A formulator's exemption statement** • **The applicant must identify the registered identical product for this category** • **The active ingredient listed on the CSF must be an EPA registered product in order to satisfy the data requirements for the active ingredient.** **If the use pattern for the proposed product differs from the currently registered product, then additional data are required and the application does not fall within this category (see applicable new use categories).** **An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient.**	4	1,159

B675 New	125	New Product MUP; registered source of active ingredient; submission of completely new generic data package; registered uses only. (2)	**An application for registration of a new microbial or biochemical pesticide manufacturing use product (MUP). New manufacturing use product is any product intended (labeled) for formulation or repackaging into an end use formulated pesticide product. The active ingredient is not a new active ingredient, but one that claims to be substantially similar or identical to another active ingredient which is currently registered (as referenced by EPA registration number) and has the selective data citation used.** All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. **An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient.**	10	8,269
B676 New	126	New product; more than one active ingredient where one active ingredient is an unregistered source; product chemistry data must be submitted; requires: 1) submission of product specific data, and 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived	**An application for registration of a new microbial or biochemical pesticide product which contains more than one active ingredient. Contains an active ingredient that is not a new active ingredient, but one that claims to be substantially similar or identical to another active ingredient which is currently registered (as referenced by EPA registration number) and has the selective data citation used and an active ingredient which is derived from an unregistered source (i.e., does not have a EPA registration number).** **An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient.** All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.	13	8,269

		supported by a scientifically-sound rationale explaining why the data requirement does not apply. (2)			
B677 New	127	New end-use non-food animal product with submission of two or more target animal safety studies; includes data and/or waivers of data for only: • product chemistry and/or • acute toxicity and/or • public health pest efficacy and/or • animal safety studies and/or • child resistant packaging (2)	**An application for registration of a new microbial or biochemical pesticide end-use animal product that is not substantially similar or identical in its uses and formulation to a product currently registered. For example, spot-on and flea collars products are generally labeled species specific, in that a product is labeled for dogs or cats, but not generally both, while shampoos and sprays may be labeled for both species (dogs and cats). All applications require the following:** • **A data matrix is required with the application.** • **Product chemistry data (Group A and B) and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. If the source of the active ingredient is not registered in this application; the decision review time line will be the longest of the associated application (see timeline for B672).** • **All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. In those cases where the product relies upon a pending inert clearance, the new companion animal studies must be conducted with the pending inert in the tested product as it is intended to be marketed and sold as the end use product.** • **Acute toxicity, public health pest efficacy, child resistant packaging data, companion animal safety data and/or requirements must be addressed by using: 1) the cite-all method, or 2) selective data citation which includes submitting required data. A rationale for a waiver or bridging of these data falls within this category.** • **Which companion animal safety studies are required is based upon the specific label claims in the proposed label. For example, if the proposed end use product label claim is to - use the product on 12 week old kittens weighing ≥3 lbs and breeding cats, then two companion animal studies are required: the first on using kittens ≥ 12 weeks of age and weighing at least 3 lbs., and a second study on pregnant and nursing adult cats. Each of these studies must demonstrate an adequate margin of safety.** • **Proposed label for the end use product** **An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an**	10	8,000

			application for a new product with an unregistered source of an active ingredient.		

			Table 14. Microbial and Biochemical Amendments		

B621	128	Amendment; Experimental Use Permit; no change to an established temporary tolerance or tolerance exemption	An application to amend an existing Experimental Use Permit for a microbial or biochemical pesticide. Amendments could include but are not limited to changing the uses, use sites, and/or acreage tested, and/or extending the length of time for completion of the experimental program. If a tolerance or tolerance exemption needs to be amended in connection with this action, you must add the cost of a petition (see B631 or B641, below, as appropriate).	7	4,631
B622 New	129	Amendment; Experimental Use Permit; petition to amend an established or temporary tolerance or tolerance exemption.	**An application to amend an existing Experimental Use Permit for a microbial or biochemical pesticide. This use requires a change/amendment to the existing tolerance/temporary tolerance or exemption for any U. S. registered active ingredient that currently has an approved tolerance/temporary tolerance or exemption for the proposed use.**	11	11,577
B641	130	Amendment of an established tolerance or tolerance exemption.	A petition to amend an established tolerance for a microbial or biochemical pesticide, with supporting data to demonstrate that dietary exposures to residues of the active ingredient at the tolerance level meet the FFDCA standard of reasonable certainty of no harm. This category includes amendments to temporary tolerances, such as those established in connection with an experimental use permit. In addition to the petition, there may be an application to register a product, or to amend an existing registered product or experimental use permit. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.	13	11,577
B680	131	Amendment; registered source of active ingredient(s); no new use(s); no changes to an established tolerance or tolerance exemption. Requires data submission. (2)	An application to amend a registration is in this category when it contains data to support a change in the label (such as use patterns, use site changes) or to add an alternate formulation, or change the basic formulation of a currently registered product. These data include but are not limited to: toxicity data, product chemistry data, manufacturing process, non-target toxicity data, efficacy/product performance, child-resistant packaging data, and data to support a new pattern of use (e.g., increased application rate, different application methods) that changes the potential for human and/or environmental risks or exposure. EPA-initiated amendments shall not be charged fees. Label amendments submitted by notification under PR Notices, such as PR Notice 95-2 and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated	5	4,631

			fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.		
B681	132	Amendment; unregistered source of active ingredient(s). Requires data submission. (2)	An application to amend a registration is in this category when it contains data to support a change in the label (such as use patterns, use site changes) or to add an alternate formulation or change the basic formulation of a currently registered product. These data include but are not limited to: toxicity data, non-target toxicity data, efficacy/product performance, child-resistant packaging data, additional (unregistered) sources of the active ingredient with supporting chemistry data, manufacturing process, efficacy (if public health pests are claimed), and data to support a pattern of use (e.g., increased application rate, different application methods) that changes the potential for human and/or environmental risks or exposure. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.	7	5,513
B683 New	133	Label amendment; requires review/update of previous risk assessment(s) without data submission (e.g., labeling changes to REI, PPE, PHI). (2)	**Modification in the label of a registered product that is not substantially similar to a currently registered product and that requires review and Agency determination of whether the existing database would support a change or modification to the amended label. Agency update of existing risk analysis/assessment may be required. No data is submitted to support this label amendment. Examples of actions in this category include: label changes to Directions for Use (including restricted entry intervals (REI), personal protective equipment (PPE), pre-harvest interval (PHI), application rate, application frequency,**	6	4,631

			application timing, addition of aerial or chemigation application methods consistent with PR Notices 87-1 and 93-2, ground water or surface water advisory statements, etc. that require risk analysis by EPA. **EPA-initiated amendments shall not be charged fees. Label amendments submitted by notification under PR Notices, such as and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees.** (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.		
B684 New	134	Amending non-food animal product that includes submission of target animal safety data; previously registered (2)	**Generally modifying an existing, previously registered label by adding additional claims for use on adults or juveniles or breeding animals of the same species. An application to amend a registered end-use pesticide animal product. For example, spot-on and flea collar products are generally labeled species specific, in that a product is labeled for dogs or cats, but not generally both, while shampoos and sprays may be labeled for both species (dogs and cats). This amendment would require the following:** • **A data matrix and data compensation forms are required with the application.** • All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. In those cases where the product relies upon a pending inert clearance, the new companion animal studies must be conducted with the pending inert in the tested product as it is intended to be marketed and sold as the end use product. • **Same species of animal previously listed on registered label.** • **If new efficacy claims are sought, then new pest efficacy data matching the claim(s) are required.** • **If the packing type has changed (e.g., spot-on vs. stripe-on) so that the dose volume is altered (new or different), new child resistant packaging data is required.** • **Which companion animal safety studies are required is based upon the specific label claims in the proposed label. For example, if the proposed end use product label claim is to use the product on 12-week old kittens weighing ≥3 lbs andon breeding**	8	8,000

			cats, then two companion animal studies are required: the first on using kittens ≥ 12 weeks of age and weighing at least 3 lbs. and a second study on pregnant and nursing adult cats. Each of these studies must demonstrate an adequate margin of safety. • **Proposed amended label for the end use product** **EPA-initiated amendment shall not be charged fees. Label amendments submitted by notification under PR Notices, such as and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees.** (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.		

			Table 15. Straight Chain Lepidopteran Pheromones		
B690	135	New active ingredient; food or non-food use (2)	An application for a product containing a new active ingredient SCLP which either has no food uses or if there is a food use, is anticipated to meet the existing tolerance exemption for SCLPs. All uses (food and/or non-food) included in any original application or petition for a first food use that otherwise satisfy the conditions for the category are covered by the base fee. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.	7	2,316
B700	136	Experimental Use Permit application; new active ingredient or new use	An application for an experimental use permit where the SCLP fits within the existing tolerance exemption for SCLPs, or with an agreement to destroy, or use only for experimental purposes, any crops treated during the experimental program. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.	7	1,159
B701	137	Extend or amend Experimental Use Permit	An application to amend an existing Experimental Use Permit for a SCLP product, which could include (but is not limited to): changing the uses, use sites, and/or acreage tested, and/or extending the length of time for completion of the experimental program.	4	1,159
B710	138	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption. No data review, or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data or authorization from data owner is demonstrated. Category includes 100% re-package of	An application for registration of a SCLP product that is substantially similar or identical in its uses and formulation to products that are currently registered, or differ from a currently registered product only in ways that would not significantly increase the risk of unreasonable adverse effects to humans or the environment. In all cases, the applicant must identify the similar registered product. Identical products are identical to another registered product and bear identical use patterns. For an identical (100% repackaging or repack) of a registered SCLP product, the data requirements are satisfied by the registered identical product. The Confidential Statement of Formula (CSF) of the proposed product must indicate the product is a 100% repack of the previously registered product. Substantially similar products must contain the same active ingredient, in substantially the same proportion. They must have the same physical state (solid, liquid, granular), and contain substantially similar other (inert) ingredients. The proposed product must have the same use	4	1,159

		registered end-use or manufacturing-use product that requires no data submission or data matrix. (3)	patterns. Identical/substantially similar products may have fewer uses, but all of its uses must have been approved for the claimed similar product. Adding or changing the use patterns (other than removal of uses) excludes the product from treatment as a substantially similar product. If the new product is a simple dilution of, or differs only by a minor change in inert ingredients from the registered product, some minor product chemistry may be required. Any cited data must have been previously reviewed and accepted by the Agency. A new product is not substantially similar to a registered product if an unregistered source of TGAI material is used to formulate the new product, or if new data, scientific literature, and/or waivers are submitted to satisfy the data requirements for the new product.		
B720	139	New product; registered source of active ingredient(s); requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (3)	An application for a new product for an existing SCLP active ingredient that includes data to support the registration. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.	5	1,159

B721	140	New product; unregistered source of active ingredient (3)	An application for a new product for a registered SCLP active ingredient; the source of the active ingredient used in the product is not registered. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.	7	2,426
B722	141	New use and/or amendment; petition to establish a tolerance or tolerance exemption (4) (5)	An application for a new use for a registered SCLP active ingredient that is not covered by the SCLP tolerance exemption. A petition to amend the established tolerance exemption for SCLPs, with supporting data to demonstrate that dietary exposures to residues of the active ingredient meet the FFDCA safety standard, i.e., there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, must accompany the application. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.	7	2,426
B730	142	Label amendment requiring data submission (4)	An application to amend an existing registration containing an SCLP active ingredient. The application contains for Agency review data that is submitted to support a change to the formulation and/or data that is necessary to support a product labeling change (e.g., use pattern, use sites, etc.) EPA-initiated amendments shall not be charged fees. Label amendments submitted by notification under PR Notices, such as PR Notice 95-2 and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees. (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10,	5	1,159

			continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.		

			Table 16. Other Actions		
B614	143	Conditional Ruling on Pre-application Study Waivers;	**A pre-application request for an active ingredient, new use, or new product. The request is for review of each study waiver associated with any of the above pre-applications. The fee**	3	2,294

New		applicant-initiated	**for this category is multiplied by each additional waiver request submitted for review. The study waiver request must include a written rationale for the study waiver and the identity of the new active ingredient (chemical structure). The application follows after the Agency has made a ruling on the study waiver(s). If a study waiver is denied, the application for the new active ingredient, new use or new product can only be submitted once the study has been conducted and the applicant has a complete application for registration. The decision on the waiver is conditional upon the review of the formal registration application and the data accompanying the application. Formal decisions or formal feedback on study waivers will not be made in meetings such as pre-registration conferences or any other pre-registration meeting with the Agency.**		
B615 New	144	Rebuttal of agency reviewed protocol, applicant initiated	**An application or submission to the EPA rebutting the conclusion(s) reached by the EPA for a previously submitted study protocol request. The science review of the study protocol is considered the completed PRIA decision on the protocol review request, so any written response contesting the conclusions in the review is considered to be a separate action and subject to a separate fee under PRIA.** This PRIA category applies to rebuttals of all protocol reviews (except HSRB protocol reviews), whether the original protocol was subject to PRIA or not. The fee for this category is multiplied by each rebuttal application that is submitted for review. PRIA fees are not applicable to pre-submission or pre-registration conferences or discussions with the EPA.	3	2,294
B682	145	Protocol review; applicant-initiated; excludes time for HSRB review	An application for approval of a study protocol. Applicant provides a written copy of the protocol along with any specific questions about the protocol. The fee for this category is multiplied by each additional protocol submitted for review. PRIA fees are not applicable for pre-submission or pre-registration conferences or discussions with the EPA.	3	2,205

			Table 17. Plant Incorporated Protectants (PIPS)		

B740	146	Experimental Use Permit application; no petition for tolerance/tolerance exemption. Includes: 1) non-food/feed use(s) for a new (2) or registered (3) PIP; 2) food/feed use(s) for a new or registered PIP with crop destruct; 3) food/feed use(s) for a new or registered PIP in which an established tolerance/tolerance exemption exists for the intended use(s). (4)	An application for a EUP using a registered PIP active ingredient, without food or feed uses, or with an agreement to destroy, or use only for experimental purposes, any crops treated during the experimental program. No issue(s) raised that would require a SAP. Example: transfer existing PIP trait by traditional breeding, such as from field corn to sweet corn.	6	86,823
B750	147	Experimental Use Permit application; with a petition to establish a temporary or permanent tolerance/tolerance exemption for the active ingredient. Includes new food/feed use for a registered (3) PIP. (4)	An application for a EUP to allow a registered PIP active ingredient to be used under controlled, field or actual use conditions so that the data required to support a federal registration can be developed to evaluate the PIP's efficacy and potential for adverse effects on human health and the environment. A temporary tolerance or exemption is set for an appropriate period of time to allow the harvest of any treated food or feed commodities during the experimental period. No issue(s) raised that would require a SAP. Example: transfer existing PIP trait by traditional breeding, such as from field corn to sweet corn.	9	115,763
B770	148	Experimental Use Permit application; new (2) PIP; with petition to establish a temporary tolerance/tolerance exemption for the active ingredient; credit 75% of B771 fee toward registration application for a new active ingredient that follows; SAP review. (5)	An application for a EUP to allow a new PIP active ingredient to be used under controlled, field or actual use conditions so that data required to support a federal registration can be developed to evaluate its efficacy and potential for adverse effects on humans and the environment. A temporary tolerance or exemption will be established for an appropriate period of time to allow the harvest of any treated food or feed commodities during the experimental period. The new PIP raises issue(s) that require a SAP review.	15	173,644
B771	149	Experimental Use Permit application; new (2) PIP; with petition to establish a temporary	An application for a EUP to allow a new PIP active ingredient to be used under controlled, field or actual use conditions so that data required for a federal registration can be developed to evaluate its	10	115,763

		tolerance/tolerance exemption for the active ingredient; credit 75% of B771 fee toward registration application for a new active ingredient that follows.	efficacy and potential for adverse effects on humans and the environment. A temporary tolerance or exemption will be established for an appropriate period of time to allow the harvest of any treated food or feed commodities during the experimental period. The new PIP raises no issue(s) that require a SAP review.		
B772	150	Application to amend or extend an Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected.	An amendment making minor changes to or extend the test period of an existing PIP EUP registration.	3	11,577
B773	151	Application to amend or extend an Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient.	An amendment making minor changes to or to extend the test period of an existing PIP EUP; an extension of an existing temporary tolerance/tolerance exemption is needed.	5	28,942
B780	152	Registration application; new (2) PIP; non-food/feed.	An application for a new PIP active ingredient for a non-food/feed use. No issue(s) identified that warrant a SAP. This category is used for full commercial registration; a seed increase registration can be obtained under B883, B884 or B885.	12	144,704
B790	153	New active ingredient; new (2) PIP; non-food/feed; SAP review required (5)	An application for a new PIP active ingredient for a non-food/feed use with issue(s) identified that warrant a SAP. This category is used for full commercial registration; a seed increase registration can be obtained under B883, B884 or B885.	18	202,585
B800	154	Registration application; new (2) PIP; with petition to establish permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption.	An application for a new PIP active ingredient for a food/feed use. A temporary tolerance or temporary exemption from a tolerance already exists to support a EUP for the active ingredient. A permanent tolerance or tolerance exemption is needed for registration. A petition to establish a tolerance or exemption from the requirement of a tolerance with supporting data must accompany the application. No issue(s) identified that warrant a SAP. This category is used for full commercial registration; a seed increase registration can be obtained	12	231,525

			under B883, B884, or B885.		
B810	155	Registration application; new (2) PIP; with petition to establish permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. SAP review. (5)	An application for a new PIP active ingredient for a food/feed use. A temporary tolerance or a temporary exemption from a tolerance already exists to support a EUP for the active ingredient. A permanent tolerance or tolerance exemption is needed for registration. A petition to establish a tolerance or exemption from the requirement of a tolerance with supporting data must accompany the application. Issue(s) identified that warrant a SAP. This category is used for full commercial registration; a seed increase registration can be obtained under B883, B884, or B885.	18	289,407
B820	156	Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient.	An application for a new PIP active ingredient for a food/feed use. A tolerance or an exemption from a tolerance must be established. No previous temporary tolerance or tolerance exemption has been established. A petition to establish a tolerance or exemption from the requirement of a tolerance with supporting data must accompany the application. No issue(s) identified that warrant a SAP. This category is used for full commercial registration; a seed increase registration can be obtained under B883, B884, or B885.	15	289,407
B840	157	Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient. SAP review. (5)	An application for a new PIP active ingredient for a food/feed use. A tolerance or an exemption from a tolerance must be established. No previous temporary tolerance or temporary tolerance exemption has been established. A petition to establish a tolerance or exemption from the requirement of a tolerance with supporting data must accompany the application. Issue(s) identified that warrant a SAP. This category is used for full commercial registration; a seed increase registration can be obtained under B883, B884, or B885.	21	347,288
B851	158	Registration application; new event of a previously registered PIP active ingredient(s); no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s).	An application for a new PIP active ingredient for a food/feed use that differs from a similar active ingredient that is registered due to its origination from a different genetic event. The new PIP active ingredient and the proposed use is already covered under an existing tolerance or tolerance exemption. No issue(s) identified that warrant a SAP.	9	115,763
B870	159	Registration application; registered (3) PIP; new product; new use; no petition since a permanent tolerance/tolerance	An application to amend a registered PIP product to add a new use site. Example: transfer existing PIP trait by traditional breeding, such as from field corn to sweet corn.	9	34,729

		exemption is already established for the active ingredient(s). (4)			
B880	160	Registration application; registered (3) PIP; new product or new terms of registration; additional data submitted; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (6) (7)	An application for a new PIP product containing a previously registered active ingredient that is in an existing registered product. No issue(s) identified that require a SAP review. Example: Stacking PIP traits within a crop using traditional breeding techniques.	9	28,942
B881	161	Registration application; registered (3) PIP; new product or new terms of registration; additional data submitted; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). SAP review. (5) (6) (7)	An application for a new PIP product containing a previously registered active ingredient that is in an existing registered product. Issue(s) identified that requires a SAP review. Example: Stacking PIP traits within a crop using traditional breeding techniques.	15	86,823
B883 New	162	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. (8)	An application for a new PIP active ingredient for seed increase/breeding purposes only. The application must propose a time limitation (expiration date) and a per-season acreage cap. A petition for a permanent tolerance/tolerance exemption is needed and must be based on a previously-established temporary tolerance or exemption (e.g., a tolerance or exemption established with an experimental use permit). If a seed increase registration is granted under this PRIA category, full commercial registration can subsequently be obtained using B890. Registrants are encouraged to consult with the Agency prior to submission of an application in this category.	9	115,763
B884 New	163	Registration application; new (2) PIP, seed increase with negotiated acreage cap and	An application for a new PIP active ingredient for seed increase/breeding purposes only. The application must propose a time limitation (expiration date) and a per-season acreage cap. A petition for a permanent tolerance/tolerance exemption is needed (not based on a previously-	12	144,704

		time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient. (8)	established temporary tolerance or exemption). If a seed increase registration is granted under this PRIA category, full commercial registration can subsequently be obtained using B890. Registrants are encouraged to consult with the Agency prior to submission of an application in this category.		
B885 New	164	Registration application; registered (3) PIP, seed increase; breeding stack of previously approved PIPs, same crop; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (9)	An application for a new PIP product for seed increase/breeding purposes only that contains a previously-registered active ingredient that is in an existing product. A new tolerance or exemption is not needed since a permanent tolerance/exemption is already in place for the previously-registered active ingredient. If a seed increase registration is granted under this PRIA category, full commercial registration can subsequently be obtained using B890.	9	86,823
B890	165	Application to amend a seed increase registration; converts registration to commercial registration; no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s).	An application to amend a registered PIP product that only allows the expansion of use from seed production to commercial registration. No issue(s) identified that require a SAP review.	9	57,882
B891	166	Application to amend a seed increase registration; converts registration to a commercial registration; no petition since a permanent tolerance/tolerance exemption already established for the active ingredient(s); SAP review. (5)	An application to amend a registered PIP product that only allows the expansion of use from seed production to commercial registration. Issue(s) identified that require a SAP review.	15	115,763
B900	167	Application to amend a registration, including actions such as extending an expiration	An application to amend a registered PIP product – except as described in B870, B890 and B891. No issue(s) identified that require a SAP review.	6	11,577

		date, modifying an IRM plan, or adding an insect to be controlled. (10) (11)	EPA-initiated amendments shall not be charged fees. Label amendments submitted by notification under PR Notices such as PR Notice 95-2 and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees.		
B901	168	Application to amend a registration, including actions such as extending an expiration date, modifying an IRM plan, or adding an insect to be controlled. SAP review. (10) (11)	An application to amend a registered PIP product, except as defined in B870, B890 and B891. Issue(s) identified that require an SAP review. EPA-initiated amendments shall not be charged fees. Label amendments submitted by notification under PR Notices such as PR Notice 95-2 and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees.	12	69,458
B902	169	PIP Protocol Review	An applicant-initiated request for Agency review of the proposed description of the study(ies) that will be performed to support the registration of a PIP	3	5,789
B903	170	Inert ingredient tolerance exemption; e.g. a marker such as NPT II, reviewed in BPPD	A petition to establish a tolerance or an exemption from tolerance for a PIP inert ingredient (for example, a marker protein).	6	57,882
B904	171	Import tolerance or tolerance exemption; processed commodities/food only (inert or active ingredient)	A petition to establish a tolerance or tolerance exemption for foods imported into the United States that contain PIP active ingredients.	9	115,763

			Table 18. Inert Ingredients and Miscellaneous Actions		
I001 New	172	Approval of new food use inert ingredient (2) (3)	An application that proposes a food use approval for an inert ingredient that is not contained in any pesticide product registered for use in or on food. The use may require the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application must contain a petition to establish tolerances or exemptions from the requirement of a tolerance for all food/feed commodities for which food use approval is sought as well as the submission of data supporting the petition. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive; uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags and food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment). Prior to a submission under this category, OPP highly recommends the applicant request a meeting with the Agency to go over data needs. Additional information regarding applications for approval of new food use inert ingredients can be found at http://www.epa.gov/opprd001/inerts/inertpetition.pdf. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients. If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered	12	18,000

			application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due data for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple inert ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those inert ingredients. If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.		
I002 New	173	Amend currently approved inert ingredient tolerance or exemption from tolerance; new data (2)	An application that proposes a change in food use approval for an inert ingredient. The use requires an amendment to a tolerance or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application must contain a petition to amend existing tolerances or exemptions from the requirement of a tolerance for all food/feed commodities for which food use approval is sought as well as the submission of data supporting the amendment (e.g., toxicity data, residue chemistry data). This category fits for changes in food use that require a change to the existing tolerance or tolerance exemption such as an increase in the limitation of the percentage of the inert ingredient under an existing tolerance exemption or the expansion of use limitations under an existing tolerance exemption such as the removal of a pre-emergent only use. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive; uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags and food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment). Prior to a submission under this category, OPP highly recommends the applicant request a meeting with the Agency to discuss data needs. Additional information regarding applications for approval of new food use inert ingredients can be found at	10	5,000

			http://www.epa.gov/opprd001/inerts/inertpetition.pdf If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due data for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I003 New	174	Amend currently approved inert ingredient tolerance or exemption from tolerance; no new data (2)	An application that proposes a change in food use for an inert ingredient. The use requires an amendment to a tolerance (or the exemption from the requirement of a tolerance) under section 408 of the FFDCA. The application submission must contain a petition to amend existing tolerances or exemptions from the requirement for all food/feed commodities for which food use approval is sought, but does not include the submission of data. This category fits for changes in food use that require a change to the existing tolerance or tolerance exemption that do not require the submission of data such as a change in the limitation of the percentage of the inert ingredient under an existing tolerance exemption or change in use limitations under an existing tolerance. Examples of food uses include: use on foods; for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive; uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags and food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment). Prior to a submission under this category OPP highly recommends the applicant request a meeting with the Agency to discuss data needs. Additional information regarding applications for approval of new food use inert ingredients can be found at	8	3,000

			http://www.epa.gov/opprd001/inerts/inertpetition.pdf If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due data for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I004 New	175	Approval of new non-food use inert ingredient (2)	An application that proposes a new non-food use for an inert ingredient that is not currently approved for non-food use and is accompanied by the submission of supporting data (e.g., toxicity data, environmental fate data, ecotoxicity data). A non-food use includes a proposed use that is not a food use as described in the food use categories. Non-food uses could include treatment of ornamentals, turf uses, structural protection, residential use, cooling tower treatments, aquatic area application (e.g., wastewater treatment), oil fields (marine and terrestrial), sewage treatment plants (water is treated prior to discharge into the environment), wood preservatives, antifoulants, ballast water, residential use (e.g., carpet sanitizer, hard surface disinfectant), commercial, institutional, industrial premise and equipment (e.g. offices, hotels, industrial buildings, nursing homes), agricultural premise treatment (e.g., farm structures, buildings and equipment, animal drinking water), materials preservatives (e.g., adhesives, coatings, plastic, fabric), industrial processes and water systems treatment (e.g., reverse osmosis water systems, recirculating cooling tower systems, evaporative condensers), medical premises and equipment (e.g., dental equipment, dental unit water lines, hospitals), HVAC, swimming pools, and spas. Prior to a submission under this category, OPP highly recommends the applicant request a meeting with the Agency to discuss data needs. Additional information regarding applications for approval of new non-food use inert	8	10,000

			ingredients can be found at http://www.epa.gov/opprd001/inerts/nonfood_inert.pdf If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due data for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I005 New	176	Amend currently approved non-food use inert ingredient with new use pattern; new data (2)	An application that proposes to amend a non-food use inert ingredient approval to include a new use pattern and is accompanied by the submission of supporting data (e.g., toxicity data, environmental fate data, ecotoxicity data). A non-food use includes a proposed use that is not a food use as described in the food use categories. Non-food uses could include treatment of ornamentals, turf uses, structural protection, residential use, cooling tower treatments, aquatic area application (e.g., wastewater treatment), oil fields (marine and terrestrial), sewage treatment plants (water is treated prior to discharge into the environment), wood preservatives, antifoulants, ballast water, residential use (e.g., carpet sanitizer, hard surface disinfectant), commercial, institutional, industrial premise and equipment (e.g. offices, hotels, industrial buildings, nursing homes), agricultural premise treatment (e.g., farm structures, buildings and equipment, animal drinking water), materials preservatives (e.g., adhesives, coatings, plastic, fabric), industrial processes and water systems treatment (e.g., reverse osmosis water systems, recirculating cooling tower systems, evaporative condensers), medical premises and equipment (e.g., dental equipment, dental unit water lines, hospitals), HVAC, swimming pools, and spas. Prior to submission under this category, OPP highly recommends the applicant request a meeting with the Agency to discuss data needs. Additional information regarding applications for approval of new non-food use inert ingredients can	8	5,000

			be found at http://www.epa.gov/opprd001/inerts/nonfood_inert.pdf If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due data for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I006 New	177	Amend currently approved non-food use inert ingredient with new use pattern; no new data (2)	An application that proposes to amend a non-food use inert ingredient approval to include a new use and does not require the submission of supporting data. A non-food use includes a proposed use that is not a food use as described in the food use categories. Non-food uses could include treatment of ornamentals, turf uses, structural protection, residential use, cooling tower treatments, aquatic area application (e.g., wastewater treatment), oil fields (marine and terrestrial), sewage treatment plants (water is treated prior to discharge into the environment), wood preservatives, antifoulants, ballast water, residential use (e.g., carpet sanitizer, hard surface disinfectant), commercial, institutional, industrial premise and equipment (e.g. offices, hotels, industrial buildings, nursing homes), agricultural premise treatment (e.g., farm structures, buildings and equipment, animal drinking water), materials preservatives (e.g., adhesives, coatings, plastic, fabric), industrial processes and water systems treatment (e.g., reverse osmosis water systems, recirculating cooling tower systems, evaporative condensers), medical premises and equipment (e.g., dental equipment, dental unit water lines, hospitals), HVAC, swimming pools, and spas. Prior to a submission under this category OPP highly recommends the applicant request a meeting with the Agency to ensure that no additional data are required. Additional information regarding applications for approval of new non-food use inert ingredients can be found at	6	3,000

			http://www.epa.gov/opprd001/inerts/nonfood_inert.pdf If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due data for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I007 New	178	Approval of substantially similar non-food use inert ingredients when original inert is compositionally similar with similar use pattern (2)	An application that proposes a new non-food use for an inert ingredient which is proposed to be compositionally similar with a similar use pattern to an approved non-food use inert ingredient. The compositionally similar non-food use inert ingredient must be cited by the applicant and have been previously assessed by OPP and approved for use. Additionally, the applicant must demonstrate that the substantially similar inert ingredient does not differ in ways that would increase the risk of unreasonable adverse effects. A non-food use includes a proposed use that is not a food use as described in the food use categories. Non-food uses could include treatment of ornamentals, turf uses, structural protection, residential use, cooling tower treatments, aquatic area application (e.g., wastewater treatment), oil fields (marine and terrestrial), sewage treatment plants (water is treated prior to discharge into the environment), wood preservatives, antifoulants, ballast water, residential use (e.g., carpet sanitizer, hard surface disinfectant), commercial, institutional, industrial premise and equipment (e.g. offices, hotels, industrial buildings, nursing homes), agricultural premise treatment (e.g., farm structures, buildings and equipment, animal drinking water), materials preservatives (e.g., adhesives, coatings, plastic, fabric), industrial processes and water systems treatment (e.g., reverse osmosis water systems, recirculating cooling tower systems, evaporative condensers), medical premises and equipment (e.g., dental equipment, dental unit water lines,	4	1,500

			hospitals), HVAC, swimming pools, and spas. Prior to a submission under this category OPP highly recommends the applicant request a meeting with the Agency to ensure that no additional data are required. Additional information regarding applications for approval of new non-food use inert ingredients can be found at http://www.epa.gov/opprd001/inerts/nonfood_inert.pdf If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due data for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I008 New	179	Approval of new polymer inert ingredient, food use (2)	An application that proposes a food use for a new inert ingredient that meets the definition of a polymer and all eligibility criteria as given under 40 CFR 723.250. The use requires the establishment of (or the exemption from the requirement of) a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemptions from the requirement for all food/feed commodities covered by the pending application. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive; uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags and food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment). Information demonstrating conformance with 40 CFR 723.250 must accompany the application. Prior to a submission under this category, OPP highly recommends the applicant request a meeting with the Agency to verify conformance with the 40 CFR 723.250 criteria.	5	3,400

			Additional information regarding applications for approval of new food use polymer inert ingredients can be found at http://www.epa.gov/opprd001/inerts/lowriskpolymer.pdf If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due data for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I009 New	180	Approval of new polymer inert ingredient, non food use (2)	An application that proposes a non-food use for a new inert ingredient which meets the definition of a polymer and all eligibility criteria as given under 40 CFR 723.250. A non-food use includes a proposed use that is not a food use as described in the food use categories. Non-food uses could include treatment of ornamentals, turf uses, structural protection, residential use, cooling tower treatments, aquatic area application (e.g., wastewater treatment), oil fields (marine and terrestrial), sewage treatment plants (water is treated prior to discharge into the environment), wood preservatives, antifoulants, ballast water, residential use (e.g., carpet sanitizer, hard surface disinfectant), commercial, institutional, industrial premise and equipment (e.g. offices, hotels, industrial buildings, nursing homes), agricultural premise treatment (e.g., farm structures, buildings and equipment, animal drinking water), materials preservatives (e.g., adhesives, coatings, plastic, fabric), industrial processes and water systems treatment (e.g., reverse osmosis water systems, recirculating cooling tower systems, evaporative condensers), medical premises and equipment (e.g., dental equipment, dental unit water lines, hospitals), HVAC, swimming pools, and spas. Information demonstrating conformance with 40 CFR 723.250 must accompany the application. Prior to a submission under this category, OPP highly recommends the applicant request a meeting	4	2,800

			with the Agency to verify conformance with the 40 CFR 723.250 criteria. Additional information regarding applications for approval of new non-food use polymer inert ingredients can be found at http://www.epa.gov/opprd001/inerts/lowriskpolymer.pdf If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due data for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I010 New	181	Petition to amend a tolerance exemption descriptor to add one or more CASRNs; no new data (2)	An application that proposes to amend a tolerance exemption descriptor by adding one or more CAS Registry Numbers (CASRNs) to an existing tolerance exemption expression in which the tolerance exemption descriptor is for grouping of closely related substances with associated CASRNs rather than a single chemical entity. (An example of such a descriptor is "Dimethylaminopropylamine, isopropylamine, ethanolamine, and triethanolamine salts of alkyl (C8-C24) benzenesulfonic acid "). An application under this category must demonstrate that the additional CASRNs to be added to the tolerance exemption expression are part of the grouping and are supported by the safety finding that was made to establish the group tolerance exemption. The application submission must contain a petition to amend existing tolerances or exemptions from the requirement but does not include the submission of data. Prior to a submission under this category OPP highly recommends the applicant request a meeting with the Agency to ensure that no additional data are required. Additional information regarding applications for approval of new food use inert ingredients can be found at http://www.epa.gov/opprd001/inerts/inertpetition.pdf	6	1,500

			If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due data for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
			MISCELLANEOUS ACTIONS		
M001 New	182	Study protocol requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient (4)	This category includes study protocols submitted to EPA, in support of an active ingredient, which propose research involving intentional exposure of a human subject, as those terms are defined in 40 CFR parts 26.1102(d), (e), and (i). Worker exposure studies and insect repellant efficacy studies are the most common types of studies submitted to OPP that may meet the regulatory definition of "research involving intentional exposure." A protocol that describes research that would provide data to populate a generic database such as the Agricultural Handler Exposure Database (AHED) or the Biocide Handler Exposure Database (BHED) will not be considered a PRIA action because the data from this type of research are intended to support many active ingredients, and the resulting study would not be submitted in support of a particular active ingredient.	9	7,200

			EPA will review both the scientific and ethical aspects of protocols covered by this category. If EPA determines that the protocol is of sufficiently high quality, EPA will submit its review of the protocol, together with the available supporting materials, to the Human Studies Review Board (HSRB). The HSRB will provide comment on both the scientific and ethical aspects of the protocol. EPA will consider the HSRB's advice in determining whether to approve the protocol.		
M002 New	183	Completed study requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient (4)	This category includes completed studies submitted to EPA, in support of an active ingredient, which report research involving intentional exposure of a human subject, as those terms are defined in 40 CFR parts 26.1102(d), (e), and (i). Worker exposure studies and insect repellant efficacy studies are the most common types of studies submitted to OPP that may meet the regulatory definition of "research involving intentional exposure." A study conducted to generate data to populate a generic database such as the Agricultural Handler Exposure Database (AHED) or the Biocide Handler Exposure Database (BHED) will not be considered a PRIA action because the data are not intended to be used to support a particular active ingredient. EPA will review both the scientific and ethical aspects of completed studies covered by this category. EPA will submit its review of the completed study, together with the available supporting materials, to the Human Studies Review Board (HSRB). The HSRB will provide comment on both the scientific and ethical aspects of the study. EPA will consider the HSRB's advice in determining whether to rely on the study. Any other covered application that is associated with and dependent upon the HSRB review will be subject to its separate fee. The decision review time for the associated action will run concurrently with that of the HSRB review but will end at the date of the latest review time.	9	7,200
M003	184	External technical peer review of new active ingredient,	Covered applications include microbial and biochemical pesticide products with PRIA decision time	12	58,000

New		product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of less than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA § 25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (5)	frames of less than 12 months, when the Agency submits to an advisory panel for comment, evaluation, and recommendations concerning the impact on health and the environment of a covered application. Examples include pesticide active ingredients, products or amendments, and uses that are based upon new or evolving technology or risks. Any covered application that is associated with and dependent upon the SAP review will be subject to its separate fee. The decision review time for the associated action will be extended by the decision review time for the SAP review.		
M004 New	185	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of greater than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA § 25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (5)	Covered applications include microbial and biochemical pesticide products with PRIA decision time frames greater than or equal to 12 months, if the Agency submits to an advisory panel for comment, evaluation, and recommendations concerning the impact on health and the environment of a covered application. Examples include pesticide active ingredients, products or amendments, and uses that are based upon new or evolving technology or risks. Any covered application that is associated with and dependent upon the SAP review will be subject to its separate fee. The decision review time for the associated action will be extended by the decision review time for the SAP review.	18	58,000
M005 New	186	New Product: Combination, Contains a combination of active ingredients from a	An application for registration of a new end-use product that contains more than one registered conventional, antimicrobial or biopesticide active ingredient. The active ingredients have never been registered as this combination before. The proposed label has the same uses as those found	9	20,000

		registered and/or unregistered source; conventional, antimicrobial and/or biopesticide. Requires coordination with other regulatory divisions to conduct review of data, label and/or verify the validity of existing data as cited. Only existing uses for each active ingredient in the combination product. (6) (7)	on the registered product labels for the single active ingredients. Each active ingredient may use a registered or unregistered source of active ingredient. If using an unregistered source of any of the active ingredients, the application for the source product would reside in the respective division for processing. All of the inerts used in the product must be approved or pending with the Agency for the applicable uses. The decision review time for the pending products will carry the longest of the pending products associated with all of the actions (i.e. the source product or the inert petition timeframes). All applications require the following: -Certification with Respect to Citation of Data and a data matrix -Product chemistry data -If applicable, acute toxicity, efficacy, and or child resistant packaging data requirements must be addressed by using; (1) the cite-all method; (2) selective data citation. A rationale for a waiver or bridging of these data can be submitted. A determination on whether data can be bridged or translated to other formulation types (for the individual active ingredients) will not be done in this category The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new combination product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
M006 New	187	Request for up to 5 letters of certification (Gold Seal) for one actively registered product.	A request for a Certificate of Registration, commonly known as a “gold seal letter”. The gold seal letter certifies that the product being exported is legally registered in the U.S. with the Agency. The company must submit a written request to the Agency, identify the company name, the EPA Registration Number and the country in which the product will be exported. The fee for this category will cover up to five (5) gold seal letters for one product.	1	250

M007 New	188	Request to extend Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(ii)	**FIFRA Section 3(c)(1)(F)(ii)** sets forth the criteria to be met for extending the exclusive use period. The threshold requirement is that the new minor use must be registered within the first 7 years of the commencement of the exclusive use period. FIFRA Section 3(c)(1)(F)(ii) states, in part: "The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after the date of enactment of this clause and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that – (I) there are insufficient efficacious alternative registered pesticides available for the use; (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health; (III) the minor use pesticide plays or will play a significant part in managing pest resistance; or (IV) the minor use pesticide plays or will play a significant part in an integrated pest management program. FIFRA Section 2(ll) states, in part: "The term "minor use" means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where— (1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or (2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and --- (A) there are insufficient efficacious alternative registered pesticides available for the use; (B) the alternatives to the pesticide use pose greater risks to the environment or human health; (C) the minor use pesticide plays or will play a significant part in managing pest resistance; or (D) the minor use pesticide plays or will play a significant part in an integrated pest management program."	12	5,000
M008	189	Request to grant Exclusive Use of data as provided by FIFRA	**FIFRA Section 3(c)(1)(F)(vi)** applies to data submitted to add a minor use to an existing registration after the initial data exclusivity period expires. It provides for a new exclusive use	10	1,500

New		Section 3(c)(1)(F)(vi) for a minor use, when a FIFRA Section 2(ll)(2) determination is required	period for data generated by an applicant or registrant to register a new minor use. It allows registrants to request at the time they submit their application for a new minor use (the use does not have exclusive use protected data) that the data be given exclusive use protection. FIFRA Section 2(ll) states, in part: "The term "minor use" means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where— (1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or (2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and --- (A) there are insufficient efficacious alternative registered pesticides available for the use; (B) the alternatives to the pesticide use pose greater risks to the environment or human health; (C) the minor use pesticide plays or will play a significant part in managing pest resistance; or (D) the minor use pesticide plays or will play a significant part in an integrated pest management program."		